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F03.019j.03

Finished Product Specification: Classic CBD Soft Gels

Description

Classic CBD Soft Gels are a dietary supplement intended for oral ingestion. Each capsule consists of a proprietary blend of hemp extract and fractionated coconut oil encapsulated in a soft gel.

General Information

Application and Use	Dietary Supplement	Packaging	120cc plastic pill packer, plastic cap, tamper-evident shrink banding, and a label
Composition	Proprietary blend of hemp extract and fractionated coconut oil	Appearance	Dark green-brown soft gels
Organic status	Extract: Not certified Fractionated coconut oil: Certified organic	Odor	None
Organic Certification	Not certified organic	Soft Gel Size	7.5
Storage and Shelf Life	2 years (730 days) from the date of production in original packaging. Store cool, dark and dry.	Soft gel material	Animal gelatin
Inventory Part	SG		

Ingredients

Ingredient	Decarboxylated Hemp Extract	Item Code	DECARB
Organic Certification	Not certified	Country of Origin	USA

Ingredient	Broad-Spectrum Distillate	Item Code	BSDIST
Organic Certification	Not certified	Country of Origin	USA

Ingredient	Organic Fractionated Coconut Oil (MCT)	Item Code	FCO
Botanical Name	Cocos nucifera	Organic Certification	Certified Organic
Plant parts used in oil	Nut	Country of Origin	Singapore

Ingredient	Gelatin	Item Code	GEL
Ingredient	Glycerin	Item Code	GLY
Ingredient	Water	Item Code	H2O

Our Low THC Hemp Extract Product is manufactured by Bluebird Botanicals according to cGMP practices.

Batch: 321 SG	
Manufacturing Date: 01/12/2023	Batch Size: 490,680 Softgels
Total Quantity Produced (packaging plan based on estimates) :	Supplier Lot Codes: E30010001
30 count bottle: 4272	Primary Ingredient: 750 SGB
60 count bottle: 1680	
120 count bottle 2181	

Potency Method: HPLC-DAD		
Total Cannabidiol ≥ 15 mg/softgel		
Tetrahydrocannabinol (THC)	< 0.2%	



F03.019j.03

Tetrahydrocannabinol (THC) per serving (mg)	≤ 0.75 mg/serving	
Tetrahydrocannabinol (THC) per container (mg)	30 count: ≤ 22.5 mg	
	60 count: ≤ 45 mg	
	120 count: ≤ 90 mg	

Heavy Metals - Method : ICP-MS			
Arsenic	< 100 ppb		
Cadmium	< 100 ppb		
Mercury	< 100 ppb		
Lead	< 100 ppb		

Mycotoxins - Method: LCMS/MS			
Total Aflatoxin (B1, B2, G1, and G2)< 20 ppb			
Aflatoxin B1	< 5 ppb		
Total Ochratoxin	< 5 ppb		

Microbiological Contamination - Method:Petrifilm, RAPID, Plating			
Total Aerobic Bacteria < 10,000 CFU/g			
Total E. coli / Coliforms	< 100 CFU/g		
Total Yeast & Mold	< 1,000 CFU/g		
Salmonella	Absent/25 g		
E. coli (STEC)	Absent/25 g		

Solvents Test Method: GC/MS, HPLC				
1-Butanol	< 5000 ppb	1-Pentanol	< 5000 ppm	
1,2 -Dichloroethane	< 1.0 ppm	1,2 - Dimethoxyethane	100 ppm	
1,4-Dioxane	< 380 ppm	2-Butanol	< 5000 ppm	
2-Ethoxyethanol	< 160 ppm	2-Methyl-1-propano (Isobutanol)	< 5000 ppm	
2-Methylbutane	< 5000 ppm	2-Methylpentane	< 290 ppm	
2-Propanol (Isopropyl Alcohol)	< 500 ppm	2,2-dimethylbutane	< 290 ppm	
2,2-Dimethylpropane (neo-pentane)	< 3000 ppm	2,3-dimethylbutane	< 290 ppm	
3-Methyl-(1)-Butanol	< 5000 ppm	3-Methylpentane	< 290 ppm	
Acetone	< 5000 ppm	Acetonitrile	< 410 ppm	
Anisole	< 5000 ppm	Benzene	< 1.0 ppm	



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F03.019j.03

Total Butanes	< 500 ppm	Butyl acetate	< 5000 ppm
Chloroform	< 1.0 ppm	Cyclohexane	< 500 ppm
Dimethyl sulfoxide (DMSO)	thyl sulfoxide (DMSO) < 5000 ppm		< 1000 ppm
Ethyl acetate	< 1000 ppm	Ethyl benzene	< 2170 ppm
Ethyl ether	< 2000 ppm	Ethyl formate	< 5000 ppm
Ethylene glycol	< 620 ppm	Ethylene oxide	1.0 ppm
Formic acid	< 5000 ppm	Hexanes (total)	< 290 ppm
Isobutyl acetate	< 5000 ppm	Isopropyl acetate	< 5000 ppm
Isopropylbenzene (Cumene)	< 70 ppm	Methanol	< 500 ppm
tert-Butylmethyl ether (Methyl-t-butyl ether	< 5000 ppm	Methyl Acetate	< 5000 ppm
Methylene chloride	< 1.0 ppm	Methylethylketone	< 5000 ppm
Methylisobutylketone	ethylisobutylketone < 4500 ppm		< 5000 ppm
n-Heptane	-Heptane < 500 ppm		< 200 ppm
n-Pentane	-Pentane < 1000 ppm		< 60 ppm
N,N-Dimethylacetamide	N-Dimethylacetamide < 1090 ppm		< 5000 ppm
Pentanes (total)	< 600 ppm	N,N-Dimethylformamide	< 880 ppm
Propyl acetate	< 5000 ppm	Propane	< 500 ppm
Tetrahydrofuran	< 720 ppm	Pyridine	< 200 ppm
Total Xylenes	< 400 ppm	Toluene	< 180 ppm
Triethylamine	riethylamine < 500 ppm		< 1.0 ppm
		-	-

Pesticides - Method: AOAC 2007.01, LCMS/MS		
Abamectin	< 70 ppb	
Acephate	< 30 ppb	
Acequinocyl	< 30 ppb	
Acetamiprid	< 50 ppb	
Aldicarb	< 100 ppb	
Allethrin	< 100 ppb	
Azadirachtin	< 500 ppb	
Azoxystrobin	< 10 ppb	
Benzovindiflupyr	< 10 ppb	
Bifenazate	< 30 ppb	



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Bifenthrin	< 100 ppb
Boscalid	< 10 ppb
Carbaryl	< 25 ppb
Captan	< 700 ppb
Chlorantraniliprole	< 30 ppb
Chlordane (cis + trans)	< 100 ppb
Chlorfenapyr	< 100 ppb
Chlorpyrifos	< 10 ppb
Clofentezine	< 10 ppb
Clothianidin	< 25 ppb
Coumaphos	< 10 ppb
Cyantraniliprole	< 10 ppb
Cyfluthrin	< 400 ppb
Cypermethrin	< 300 ppb
Cyprodinil	<10 ppb
Daminozide	< 50 ppb
Deltamethrin	<500 ppb
Diazinon	< 10 ppb
Dichlorvos	
	<50 ppb
Dimethoate	< 10 ppb
Dimethomorph	< 50 ppb
Dinotefuran	<50 ppb
Dodemorph	<50 ppb
Endosulfan I (alpha)	<50 ppb
Endosulfan II (beta)	<50 ppb
Endosulfan sulfate	<50 ppb
Ethoprophos	< 10 ppb
Etofenprox	< 10 ppb
Etoxazole	< 10 ppb
Etridiazole	<50 ppb
Fenhexamid	< 100 ppb
Fenoxycarb	< 10 ppb
Fenpyroximate	<20 ppb
Fensulfothion	<10 ppb
Fenthion	<10 ppb
Fenvalerate	<200 ppb
Fipronil	< 10 ppb
Flonicamid	<25 ppb
Fludioxonil	<10 ppb
Fluopyram	<10 ppb
Hexythiazox	<10 ppb
Imazalil	< 10 ppb
Imidacloprid	< 10 ppb
Innuaciophu	· 10 pps



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Kinoprene	<50 ppb
Kresoxim Methyl	< 10 ppb
Malathion	< 10 ppb
Metalaxyl	< 10 ppb
Methiocarb	< 10 ppb
Methomyl	<pre></pre>
Methoprene	<1000 ppb
Mevinphos	< 25 ppb
MGK-264	<50 ppb
	<10 ppb
Naled	< 100 ppb
Novaluron	<25 ppb
Oxamyl	< 500 ppb
Paclobutrazol	< 10 ppb
Parathion-methyl	< 30 ppb
Permethrin	< 40 ppb
Phenothrin	<25 ppb
Phosmet	< 20 ppb
Piperonyl butoxide	<200 ppb
Pirimicarb	<10 ppb
Prallethrin	< 50 ppb
Propiconazole	< 10 ppb
Propoxur	< 10 ppb
Pyraclostrobin	<10 ppb
Pyrethrins (total)	< 25 ppb
Pyridaben	< 20 ppb
Quintozene	<20 ppb
Resmethrin	<20 ppb
Spinetoram	< 10 ppb
Spinosad	< 10 ppb
Spirodiclofen	<250 ppb
Spiromesifen	< 30 ppb
Spirotetramat	< 10 ppb
Spiroxamine	< 10 ppb
Tebuconazole	< 10 ppb
Tebufenozide	<10 ppb
Teflubenzuron	<25 ppb
Tetrachlorvinphos	<10 ppb
Tetramethrin	<50 ppb
Thiacloprid	< 10 ppb
Thiamethoxam	< 10 ppb
Thiophanate-Methyl	<30 ppb
Trifloxystrobin	< 10 ppb



DISCLOSURE OF PRODUCT COMPONENTS: OUR LOW THC HEMP EXTRACT PRODUCTS ARE BLENDED USING A COMBINATION OF FULL SPECTRUM CANNABINOID EXTRACTS, ORGANIC CARRIER OILS AND ENCAPSULATED IN A SOFTGEL COATING, THE CONTENTS, IDENTITY AND PURITY OF WHICH HAVE BEEN TESTED USING A VARIETY OF METHODS, INCLUDING AOAC-APPROVED METHODS OF ANALYSIS. AOAC INTERNATIONAL IS AN INDEPENDENT, INTERNATIONALLY RECOGNIZED 501(C)(3) NOT-FOR-PROFIT ASSOCIATION WHOSE ANALYTICAL STANDARDS APPLY TO A BROAD RANGE OF INDUSTRIES INCLUDING FOODS, BEVERAGES AND DIETARY SUPPLEMENTS. INGREDIENT AND SERVICE PROVIDERS HAVE BEEN QUALIFIED BY AN INTERNAL QUALITY MANAGEMENT TEAM ACCORDING TO A CGMP-COMPLIANT PROTOCOL. THE QUALIFICATION OF A SUPPLIER ENTAILS INGREDIENT TESTING INCLUDING BUT NOT LIMITED TO THE FOLLOWING ASSAYS: FATTY ACIDS (OFFICIAL METHODS OF ANALYSIS OF AOAC INTERNATIONAL, 18TH ED., METHODS 922.06 AND 954.02), PEROXIDE VALUE (AOAC INTERNATIONAL, OFFICIAL METHODS 95.33 AND 983.23), YEAST AND MOLD ANALYSIS (AOAC INTERNATIONAL, OFFICIAL METHOD 997.02), AEROBIC PLATE COUNT (AOAC INTERNATIONAL, OFFICIAL METHOD 990.12), ELEMENTS (AOAC INTERNATIONAL, OFFICIAL METHODS 2011.19 AND 993.14), REGULATED MYCOTOXINS (CITATION: ANALYTICAL AND BIOANALYTICAL CHEMISTRY, 402:2675-2686), E. COLI AND COLIFORMS (AOAC INTERNATIONAL, OFFICIAL METHOD 991.14), MULTI-RESIDUE ANALYSIS (AOAC INTERNATIONAL, OFFICIAL METHOD 2007.01), GLUTEN (AOAC INTERNATIONAL, OFFICIAL METHOD 2012.01), RESIDUAL SOLVENTS (UNITED STATES PHARMACOPEIA METHOD 467). THE AFOREMENTIONED METHODS OF ANALYSIS UTILIZE BUT ARE NOT NECESSARILY LIMITED TO QUANTIFICATION BY HPLC, UPLC/MS, GC/MS, IAC, SFC, ICP-MS. INGREDIENT CONSISTENCY IS ADDITIONALLY EVALUATED THROUGH REGULAR ORGANOLEPTIC SCREENING TO CONTROL TASTE. ODOR, COLOR AND CONSISTENCY. THE FOLLOWING SUPPLIERS/ MANUFACTURERS/SERVICE PROVIDERS HAVE BEEN QUALIFIED BY INTERNAL QUALITY MANAGEMENT: HEMP PRODUCTION SERVICES, SUPPLIER OF ORGANIC HEMP SEED OIL, JEDWARDS INTERNATIONAL, SUPPLIER OF ORGANIC HEMP SEED OIL, FRESH HEMP FOODS, SUPPLIER OF ORGANIC HEMP SEED OIL, ZIVO INC, MANUFACTURER/SUPPLIER OF HEMP EXTRACTS, SOFTGEL TECHNOLOGIES, MANUFACTURER OF GEL CAPSULES. PROPRIETARY LOW THC HEMP EXTRACT PRODUCTS ARE MANUFACTURED BY BLUEBIRD BOTANICALS ACCORDING TO CGMP PRACTICES. ALL PRODUCTS ARE TESTED FOR MYCOTOXINS, PESTICIDES, ELEMENTS, RESIDUAL SOLVENTS, TERPENE PROFILES AND CANNABINOID POTENCY TO CONTROL ADHERENCE TO PRODUCT SPECIFICATIONS AND GUARANTEE CONFORMITY TO THE STRICT DEFINITION OF INDUSTRIAL HEMP (<0.3% DELTA9-THC, INCLUDING PRECURSORS). THIRD PARTY LABORATORY ANALYSIS IS CONDUCTED BY BOTANACOR SERVICES, ACS LABORATORIES, AND EUROFINS. ISO ACCREDITED (ISO 17025) ASSAYS ARE PROVIDED BY BOTANACOR, ACS, AND EUROFINS. SEE PRODUCT SPECIFICATION SHEET ABOVE FOR PRODUCT/INGREDIENT BATCH INFORMATION AND PROJECTED PACKAGING PLAN. ALL SUPPLIERS OF PACKAGING SUPPLIES HAVE BEEN QUALIFIED ACCORDING TO CGMP STANDARDS.

Version #	Date Revised	Revised By	Revision
0	12/7/2020	КОІ	Original, added to document registry
1	1/11/2021	коі	Updated Plant Parts
2	7/12/2021	коі	Updated with CDPHE Requirements (not pesticides)
3	07/19/2022	SB	Updated to match new lab and state analyte limits, added Inventory Part, changed listed name, updated Description, updated ingredients.