

Technical Data Sheet



Product Code: 4020B1065
Product Description: 40/20 EE Fish Oil 1065 mg cap
Document Code: 111683

Country of Origin: Canada
Fish Type [Species]: Anchovy [*Engraulis ringens*], Sardine [*Sardinops sagax sagax*] or Mackerel [*Trachurus symmetricus*] or a combination thereof.

Description: Oblong, uncoloured, translucent #20-#22 soft gel capsules containing a clear light yellow oil, without sediment at room temperature (21°C).

Antioxidant: Identity Preserved Mixed Natural Tocopherols
Min 2 mg/g (based on oil input)

Shelf Life: 3 years from date of manufacture

Standard Packaging: Sealed plastic bag within a sealed cardboard box.

Storage: This product maintains stability when stored in a tight, light resistant container and in a cool, dry place at a temperature between 15°C and 25°C.

Active Ingredients

Common Name	Specification	Method
EPA (%) based on 24 peak analysis	Min. 40%	
EPA (mg/g as EE)	Min. 420 mg/cap	
EPA (mg/g as FFA)	Min. 380 mg/cap	
DHA (%) based on 24 peak analysis	Min. 20%	EP2003: 1352 Method 2.4.29 (modified)
DHA (mg/g as EE)	Min. 210 mg/cap	
DHA (mg/g as FFA)	Min. 190 mg/cap	
Omega-3 (%) ¹ based on 24 peak analysis	Min. 60%	
Total Omega-3 (mg/g)	Min. 630 mg/cap	

¹ Sum of 18:3w3, 18:4w3, 20:4w3, 20:5w3, 21:5w3, 22:5w3, 22:6w3

Fill Weight

Fill Weight	959 - 1172 mg /capsule	In-House Method
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Analytical Data

Test	Specification	Method
Colour	Max. 6	Gardner Colour
Disintegration:	Max. 30 min	USP <701> or USP <2040> ⁴
Free Fatty Acid (as % Oleic)	Max. 1.5 %	AOCS Cd 3D-63 (modified)
Acid Value (AV)	Max. 3.0 mg KOH/g	AOCS Cd 3D-63 (modified)
p-Anisidine Value (p-AV)	Max. 20	AOCS Cd 18-90
Peroxide Value (PV)	Max. 5 meq/kg	AOCS Cd-8-53
Moisture	Max. 0.1 %	AOCS Ca 2e-84 (modified)
TOTOX	Max. 26	

Capsule Shell Ingredients (typical results)

Gelatin Type	Bovine	
Gelatin - NF (mg)	269.0	As per encapsulator
Glycerin - USP (mg)	120.1	As per encapsulator
Purified Water - USP (mg)	29.3	As per encapsulator
Total Shell	418.4	

* Note: Due to encapsulation variation, ingredients and total shell based on theoretical input, actuals may vary.

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Microbiological (test results provided by encapsulator)

Test	Specification	Methods
Salmonella	Negative	USP<62> or USP <2022> ⁴
E. Coli	Negative	USP<62> or USP <2022> ⁴
S. aureus	Negative	USP<62> or USP <2022> ⁴
P. aeruginosa	Negative	USP <61> ⁴
Total Count	Max. 3000 CFU/g	USP <61> or USP <2021> ⁴
Yeast/Mold	Max. 300 CFU/g	USP <61> or USP <2021> ⁴
Coliforms	Max. 10 MPN/g or CFU/g*	BAM 8 Ed. ⁴

* units reported on the CofA will be as per the encapsulator used.

Contaminant Data (based on input oil)

Test	Specification	Methods
Dioxins & Furans: PCDDs & PCDFs	Max. 1.0 pg WHO-PCDD/F-TEQ/g	QMA504-171 ⁴
Dioxin-Like PCBs ²	Max. 3 pg WHO-Dioxin Like PCBs-TEQ/g	US EPA 1668 (modified) ⁴
Sum Dioxins & Furans + Dioxin Like PCBs	Max 4.0 pg WHO-PCDD/F + Dioxin Like PCBs-TEQ/g	Dioxins & Furans + Dioxin Like PCBs
PAHs: Benzo(a)pyrene	Max. 2.0 ppb (µg/kg)	in accord. with NEN-ISO-15302 ⁴
PCBs ³	< 0.09 ppm (mg/kg)	US EPA 1668 (modified) ⁴
Total PCBs (Canada only)	Max. 0.1 ppm (mg/kg)	US EPA 1668 (modified) ⁴
Arsenic	< 0.1 ppm (mg/kg)	US EPA 200.7 & 200.8 (modified) ⁴
Lead	< 0.05 ppm (mg/kg)	US EPA 200.7 & 200.8 (modified) ⁴
Cadmium	< 0.01 ppm (mg/kg)	US EPA 200.7 & 200.8 (modified) ⁴
Mercury	< 0.005 ppm (mg/kg)	US EPA 245.6 ⁴
Strontium (Canada only)	Max. 0.5 ppm (mg/kg)	US EPA 200.7 & 200.8 (modified) ⁴

Contaminant Testing Frequency: Tested 3 times per annum. They will be listed on the CofA (Certificate of Analysis) as compliant or updated with the most recent test results.

² Sum of IUPAC No. 81, 77, 126, 169, 105, 114, 118, 123, 156, 157, 167, 189

³ Sum of IUPAC No. 28, 52, 101, 118, 138, 153, 180

⁴ 3rd Party Testing

QA Approval: Kim Pattenden-Dawson Approval Date: Apr 30/09
 Product Manager Approval: [Signature] Approval Date: May 1/09

Customer Approval

We agree to accept deliveries that comply to this specification, please complete the following section and return it to us at salesorders@ocean-nutrition.com or fax to 902 480 3202.

Company Name: _____
 Name: _____ Position: _____
 Signature: _____ Date: _____



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