Fish Oil Supplements

GOALS

The aim of this study was to evaluate the quality and safety of commercially available fish oil supplements. The goals were to 1) determine the levels of omega-3 fatty acids, including eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA); total oxidation (p-Anisidine and peroxide); the heavy metals arsenic, cadmium, lead, and mercury; dioxins and PCBs; and chlorinated paraffins, and test for compliance with USP disintegration, and 2) assess any associated quality issue and health risk. We tested 53 samples, representing 2 to 3 unique lots each of 21 products of adult's, women's prenatal, and children's fish oil supplements. The products tested were selected from multiple retailers and purchased between September 2024 and January 2025 from supermarkets and health food stores in Connecticut, New Jersey, and New York, as well as online.

To be clear, Consumer Reports conducts its testing to provide consumers with advice to inform their decision-making. We do not perform compliance or regulatory testing, and our results are not meant to be viewed as such.

SAMPLE PREPARATION

The samples were transferred into brown polyethylene jars, blind coded to preserve their identities, and shipped to three independent, accredited laboratories. At the laboratories, sample preparation or mixing was performed in fume hoods known to be free of contamination by trace metals and the other target contaminants. Water, sample containers, and other materials used for the analyses were monitored for contamination to account for any biases in sample results.

TESTING

Analysis for Fatty Acids by Hydrolytic Extraction and Gas Chromatographic (GC) Separation

- Samples were prepared and analyzed in accordance with the Association of Official Analytical Chemists (AOAC) Methods 996.06 and 945.44.

Analysis for P-Anisidine Values, Peroxide Values, and Total Oxidation Values by Spectrophotometric and Titration Methods

- All samples were prepared and analyzed following the official methods of the American Oil Chemists' Society (AOCS) AOCS 18-90 and AOCS 8-53.

Analysis for Total Arsenic, Cadmium, and Lead by Inductively Coupled Plasma Mass Spectrometry (ICP-MS)

- All samples were prepared and analyzed in accordance with the Association of Official Analytical Chemists (AOAC) Method 2015.01.

Analysis for Total Mercury by Cold Vapor Atomic Fluorescence Spectroscopy (CVAFS)

- All samples were prepared and analyzed in accordance with the Environmental Protection Agency (EPA) Method EPA 1631E.

Analysis for Chlorinated Dibenzo-p-dioxins (CDDs) and Dibenzofurans (DBFs) by High-Resolution Gas Chromatography Tandem Mass Spectrometry (HRGC/HRMS)

- All samples were prepared and analyzed in accordance with the Environmental Protection Agency (EPA) Method EPA 1613B.

Analysis for Polychlorinated Biphenyls (PCBs), Including 12 Dioxin-Like PCBs, by High-Resolution Gas Chromatography Tandem Mass Spectrometry (HRGC/HRMS)

- All samples were prepared and analyzed in accordance with the Environmental Protection Agency (EPA) Method EPA 1668A.

Analysis for Short-Chain, Medium-Chain, and Long-Chain Chlorinated Paraffins, Including 12 Dioxin-Like PCBs, by Liquid Chromatography Mass Spectrometry (LC-MS/MS)

- All samples were prepared and analyzed in accordance with the laboratory's internal SOP and Method.

Analysis for the United States Pharmacopeia (USP) Rupture Test and/or Delayed Release Test

- All samples were prepared and analyzed in accordance with the USP Method <2040>.

Where applicable, sample analysis was preceded by at least a five-point calibration curve spanning the entire concentration range of interest. Calibration curves were performed at the beginning of each analytical day and verified during analysis. All testing conformed to the quality control criteria and performance requirements set in cited official methods, as well as to those in ISO 17025.

DATA ANALYSIS AND RISK ASSESSMENT

We followed the USP acceptance or pass criteria to assess compliance of the tested pills with the USP rupture test. We estimated percent label claims of EPA, DHA, and total omega-3 fatty acids using the weight of a pill and our test results, the estimated daily consumption of the supplements using the label daily dose recommendations, and the associated daily intakes of EPA, DHA, total omega-3 fatty acids, lead, mercury, dioxins and PCBs, chlorinated paraffins from the consumption estimates, our test results,

and the average body weights of U.S. adults and children 3 to 6 years old. We used the recommended body weights from the Environmental Protection Agency (EPA) 2011 Exposure Factors Handbook.[1] To pass our evaluation, a product had to meet all the passing criteria and not exceed any of the standards or health-based exposure limits.

CR Criteria for Passing Evaluation

Analyte/ Contaminant	Source	Value (Unit)
EPA/DHA	CR	≥ 90% of Label
Total Omega-3 FA	CR	≥ 90% of Label
Total Omega-3 FA, EPA/DHA	USP Monograph, USP 32/NF 27[2]	≥ 28% Total Omega-3 FA; ≥ 13% EPA; ≥ 9% DHA of Label
USP Disintegration	USP <2040>[3]	Pass (Capsules, Coated Capsules)
Lead	GOED Monograph[4]	≤ 0.05 ug/g Oil
Mercury	GOED Monograph[4]	≤ 0.1 ug/g Oil
Anisidine Value	GOED Monograph[4]	≤ 20.0
Peroxide Value	GOED Monograph[4]	≤ 5.0
Total Oxidation Value	GOED Monograph[4]	≤ 26.0
Total Dioxins	EU Maximum Levels[5]	≤ 5.0 pg WHO TEQ/g Oil
Total Dioxins + Dioxin-Like PCBs	EU Maximum Levels[5]	≤ 20.0 pg WHO TEQ/g Oil

GOED=Global Organization for EPA and DHA Omega-3s; EU=European Union.

We compared our estimated daily intakes with health-based limits in the table on the next page using the following equation:

- % CR Level of Concern = (Estimated Daily Intake/ Exposure Limit) x 100

This equation derives from the public health concept of hazard quotient and the following equation: Hazard Quotient (HQ) = Estimated Daily Intake/Exposure Limit

A % CR Level of Concern greater than 100 indicates a comparatively higher health risk at this consumption level.

We used the California Office of Environmental Health Hazard Assessment (OEHHA) Maximum Allowable Dose Levels (MADL) as our benchmarks for CR's levels of concern for lead. MADLs are levels established through California's Proposition 65 law. CR uses these values because the standards are the most protective of health. A measured level greater than 100% of CR level of concern indicates that consumption of that serving amount per day would pose a comparatively higher health risk.

However, while we use the MADLs involved in Prop 65, we approach our exposure assessment differently from what's outlined in Prop 65. Prop 65 takes into consideration consumers' average exposure over time and dietary frequency to calculate whether a product exceeds the MADL and requires a warning label. By contrast, Consumer Reports assumes the label recommended daily serving of the product in its risk assessment calculations. This difference in methodology means no Prop 65 judgments can be made from CR's findings. Our results are meant to provide guidance on which products have comparatively higher levels of lead, not to identify the point at which lead exposure will have measurable harmful health effects, or to assess compliance with California law.

For chlorinated paraffins, chemical substances for which health experts have deemed it inappropriate to establish a health-based guidance value or a safe exposure limit, we estimated the margins of exposure (MOE) as the ratio of the $BMDL_{10}$ and the estimated daily intake of the total SCCPs or MCCPs using the following equation:

- MOE = $BMDL_{10}$/Estimated Daily Intake

An MOE greater than 1000 indicates no toxicological or health concern at this consumption level. MOE below 1000 indicates a comparatively higher risk of adverse health effects and a concern for public health.

[1] United States Environmental Protection Agency. Exposure Factors Handbook, Chapter 8 (2011 Edition). Available here: https://www.epa.gov/expobox/exposure-factors-handbook-2011-edition. [2] USP Monograph for Fish Oil Containing Omega-3 Acids Capsules and USP Fish Oil Containing Omega-3 Acids Delayed-Release Capsules. [3] Disintegration and Dissolution of Dietary Supplements, USP <2040>. [4] GOED (Global Organization for EPA and DHA) Voluntary Monograph. Omega-3 Fatty Acids. Version 8.1. Issue Date January 6, 2022. [5] Eurofins. Dioxins and PCBs in feed products: Revised Maximum levels and action levels. European Union maximum values for feed products.

Cancer and Non-Cancer Health Risks From Estimated Intakes of Lead, Methyl Mercury, Chlorinated Paraffins, Dioxins, Dioxin-Like PCBs, and PCBs

Selected Health-Based Exposure Limits			
Heavy Metal	**Source**	**Endpoint and Basis for Limit**	**Value (Unit)**
Lead	OEHHA (2017)	OEHHA Proposition 65 Maximum Allowable Dose Level (MADL) for Chemicals Causing Reproductive Toxicity (total lead, oral exposure)	0.5 ug/day
Methyl Mercury	EPA (Updated 2001)	Non-cancer oral reference dose based on developmental neuropsychological impairment	0.1 ug/kg-day
Total Dioxins and Dioxin-Like PCBs	EFSA (2019)	EFSA Tolerable Daily Intake (TDI) for semen quality	2.0 pg WHO TEQ/kg bw/week
Total PCBs	OEHHA (2017)	OEHHA Proposition 65 No Significant Risk Levels (NSRLs) for Carcinogens (oral exposure)	0.09 ug/day
Chlorinated Paraffins — short-chain chlorinated paraffins (SCCPs), medium-chain chlorinated paraffins (MCCPs), long-chain chlorinated paraffins (LCCPs)	EFSA (2019)	Increased incidence of nephritis in male rats (SCCPs); Increased relative kidney weights in male and female rats (MCCPs)	2.3 mg/kg bw/day ($BMDL_{10}$ for SCCPs); 36 mg/kg bw/day ($BMDL_{10}$ for MCCPs); MOE ≥ 1000 indicate no health concern

EFSA = European Food Safety Agency; $BMDL_{10}$ = Benchmark dose lower limit associated with a 10% increase in specific adverse effect; MOE = Margin of Exposure.