NSF International Standard for Dietary Supplements —

Dietary supplements

-
-
-

2 Normative references

The following documents contain provisions that, through reference in this text, constitute provisions of this Standard. At the time this Standard was written, the editions indicated were valid. All documents are subject to revision, and parties are encouraged to investigate the possibility of applying the most recent edition of the document indicated below.

-
-
-

GOED, *Voluntary Monograph*[2]

Health Canada, *Fish Oil Monograph*[3]

-
-
-

USP, *Dietary Supplements Compendium (DSC)*[4]

USP, *Glycerin Monograph*[4]

USP, ~~-~~*United States Pharmacopeia–National Formulary (USP–NF)*[4] ~~[1]United States Pharmacopeia, USP 29-NF 24~~

-
-
-

~~[1] [2]~~ ~~GOED Voluntary Monograph Omega-3 (v.3), July 2006.~~ ~~Council for Responsible Nutrition, Omega 3 Fatty Acids Voluntary Monograph, March 2006. Dioxin limits include the sum of polychlorinated dibenzo *para* dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) and are expressed in World Health Organization (WHO) toxic equivalents using WHO-toxic equivalent factors (TEFs). This means that analytical results relating to 17 individual dioxin congeners of toxicological concern are expressed in a single quantifiable unit: TCDD toxic equivalent concentration or TEQ.~~ Global Organization for EPA and DHA Omega-3s (GOED), 1075 Hollywood Ave., Salt Lake City, UT 84105 <www.goedomega3.com>.

~~[2]~~ [3] Health Canada, Address Locator 0900C2, Ottawa, Ontario K1A 0K9 Canada <www.hc.sc.gc.ca >.

~~[2]~~ [4] ~~USP Glycerin monograph,~~ United States Pharmacopeia (USP), 12601 Twinbrook Parkway, Rockville, Maryland 20852 <www.usp.org>. ~~,May 2009~~

5.3.6 Industrial Contaminants

5.3.6.1 Contaminants in Fish Oil

For ingredients and products containing natural fish oil, manufacturers shall have controls in place to screen for polychlorinated biphenyls (PCBs), polychlorinated dibenzo-para-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and dioxin-like PCBs in the oil ingredient.

The content of dioxins and furans expressed as the sum of PCDDs and PCDFs shall not exceed 2 pg WHO-TEQ per gram of oil and dioxin-like PCBs shall not exceed 3 pg WHO-TEQ per gram of oil.[2] The dioxin-like PCBs shall include the IUPAC congeners 77, 81, 105, 114, 118, 123, 126, 156, 157, 167, 169 and 189.

In the event that the per gram limits for dioxins and furans or dioxin-like PCBs are exceeded, a daily dose based limit will be applied. The daily dose of the sum of the dioxins/furans and the dioxin-like PCBs shall not exceed 20 pg.[3]

> NOTE - The acceptable daily dose of 20 pg/day is based on the Health Canada Fish Oil Monograph limit of 2 pg/kg b.w./day. Due to the targeted marketing of fish oils to children, a body weight of a child (10 kg) was used to derive the daily dose of 20 pg/day for dioxin/furan (PCDD and PCDF).

Total PCBs shall not exceed 0.09 mg/kg of oil (w/w). Total PCBs shall, at a minimum, include IUPAC congeners 28, 52, 101, 118, 138, 153, and 180.

5.3.6.2 Contaminants in Glycerin

For ingredients and products containing glycerin, manufacturers shall have good manufacturing controls in place to verify that any specific lot of glycerin used in the manufacture or preparation of products is tested for diethylene glycol (DEG).

Diethylene glycol in glycerin raw materials shall not exceed 0.1% as stated in the USP Glycerin monograph[2]

-
-
-

7.5 Test methods for industrial contaminants

7.5.1 Test methods for Fish Oil

Testing of fish oil samples for PCBs and dioxin-like PCBs shall be performed utilizing a high resolution gas chromatography-high resolution mass spectrometry (HRGC-HRMS) method, EPA Method 1668, Revision A: Chlorinated Biphenyl Congeners in Water, Soil Sediment and Tissue by HRGC-HRMS. Testing of fish oil samples for dioxins and furans shall be performed utilizing a high resolution gas chromatography-high resolution mass spectrometry (HRGC-HRMS) method, EPA Method 1613, Revision B: Tetra- through Octa-Chlorinated Dioxins and Furans by Isotope Dilution HRGC-HRMS. The preparation steps for these methods are applicable to water, soil, fish tissue and other environmental samples. For the analysis of fish oil, for both methods, the preparation of the sample involves dissolution in hexane followed by column based sample clean-up steps prior to the described instrumental analysis.

Manufacturers shall meet this testing requirement by one of the following routes:

– through the use of compliant ingredients as demonstrated by third party testing; or
– performing testing utilizing a laboratory accredited for PCBs, Dioxin and Furans under ISO 17025 and providing the sample results, data, and quality control results, for review to support compliance

7.5.2 Test methods for Glycerin

Testing for diethylene glycol in the glycerin raw material shall be performed utilizing identity tests, including the gas chromatographic limit test for DEG, which appear in the USP Glycerin monograph or other method that is scientifically valid and demonstrated as fit for purpose.

Manufacturers shall meet this testing requirement by providing testing documentation which can be reviewed and clearly shows the association of the test results with the lot of finished product material being certified.

Manufacturers shall meet this test requirement by either providing their own data, providing data from their qualified supplier(s) or acquiring third party test data.

-
-
-