



*NSF International Standard /
American National Standard*

NSF/ANSI 173 - 2013

Dietary Supplements



NSF International, an independent, not-for-profit, non-governmental organization, is dedicated to being the leading global provider of public health and safety-based risk management solutions while serving the interests of all stakeholders.

This Standard is subject to revision.
Contact NSF to confirm this revision is current.

Users of this Standard may request clarifications and interpretations, or propose revisions by contacting:

Chair, Joint Committee on Dietary Supplements
NSF International
789 North Dixboro Road, P.O. Box 130140
Ann Arbor, Michigan 48113-0140 USA
Phone: (734) 769-8010 Telex: 753215 NSF INTL
FAX: (734) 769-0109
E-mail: info@nsf.org
Web: <http://www.nsf.org>

NSF International Standard/
American National Standard
for Dietary Supplements —

Dietary supplements

Standard Developer

NSF International

American National Standards Institute

Designated as an ANSI Standard

August 19, 2013

American National Standards Institute

Prepared by
The NSF Joint Committee on Dietary Supplements

Recommended for Adoption by
The NSF Council of Public Health Consultants

Adopted by
NSF International
January 2003

Revised July 2005
Revised August 2006
Revised July 2007
Revised April 2008
Revised September 2008
Revised April 2009
Revised November 2010
Revised September 2011
Revised August 2012
Revised February 2014

Published by

NSF International
PO Box 130140, Ann Arbor, Michigan 48113-0140, USA

For ordering copies or for making inquiries with regard to this Standard, please reference the designation “NSF/ANSI 173 – 2013.”

Copyright 2014 NSF International

Previous editions © 2012, 2011, 2010, 2009, 2008, 2007, 2006, 2005, 2003

Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from NSF International.

Printed in the United States of America.

Disclaimers¹

NSF, in performing its functions in accordance with its objectives, does not assume or undertake to discharge any responsibility of the manufacturer or any other party. The opinions and findings of NSF represent its professional judgment. NSF shall not be responsible to anyone for the use of or reliance upon this Standard by anyone. NSF shall not incur any obligation or liability for damages, including consequential damages, arising out of or in connection with the use, interpretation of, or reliance upon this Standard.

NSF Standards provide basic criteria to promote sanitation and protection of the public health. Provisions for mechanical and electrical safety have not been included in this Standard because governmental agencies or other national standards-setting organizations provide safety requirements.

Participation in NSF Standards development activities by regulatory agency representatives (federal, local, state) shall not constitute their agency's endorsement of NSF or any of its Standards.

Preference is given to the use of performance criteria measurable by examination or testing in NSF Standards development when such performance criteria may reasonably be used in lieu of design, materials, or construction criteria.

The illustrations, if provided, are intended to assist in understanding their adjacent standard requirements. However, the illustrations may not include **all** requirements for a specific product or unit, nor do they show the only method of fabricating such arrangements. Such partial drawings shall not be used to justify improper or incomplete design and construction.

Unless otherwise referenced, the annexes are not considered an integral part of NSF Standards. The annexes are provided as general guidelines to the manufacturer, regulatory agency, user, or certifying organization.

¹ The information contained in this Disclaimer is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI's requirements for an ANS. Therefore, this Disclaimer may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to the Standard.

This page is intentionally left blank.

Contents

1	General	1
1.1	Purpose	1
1.2	Scope	1
1.3	Formulation submission	1
2	Normative references	2
3	Definitions	5
4	Labeling and literature requirements	7
5	Product requirements	7
5.1	Identity	7
5.2	Quantity	7
5.3	Contaminants	8
5.4	Disintegration	10
5.5	Oils	11
6	Test methods used by testing laboratories for identification and quantification of ingredients – raw materials and finished products	11
6.1	Identification test methods	11
6.2	Quantification test methods	12
7	Test methods used by testing laboratories for detection of contaminants – raw materials and finished products	15
7.1	Test methods for metals	15
7.2	Pesticides	15
7.3	Test methods for microbiological contaminants	16
7.4	Test methods for chemical contaminants	17
7.5	Test methods for industrial contaminants	18
8	Good Manufacturing Practices	19
8.1	Written recall procedures	19
8.2	Compliance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	19
	Annex A	1
	Annex B	1
	Annex C	1

This page is intentionally left blank.

Foreword²

The purpose of NSF/ANSI 173 is to serve as an evaluation tool for analyzing dietary supplements. Certification to this Standard serves as a communication tool between manufacturers of ingredients and finished product, retailers, healthcare practitioners, and consumers. This Standard provides test methods and evaluation criteria to allow for the determination that a dietary supplement contains the ingredients claimed on the label, either qualitatively or quantitatively, and that it does not contain specific undeclared contaminants. In some instances, validated laboratory methods are not yet available for analyzing certain ingredients. In such cases, new methods will be added to this Standard as they become available.

NSF/ANSI 173 was developed with participation from the dietary supplements industry, public health regulators, and distributors of dietary supplements. Participation and technical guidance was provided by representatives of the American Herbal Products Association, the American Pharmaceutical Association, the Consumer Healthcare Products Association, the Council for Responsible Nutrition, the National Institutes of Health, and the National Nutritional Foods Association.

This edition of the Standard (NSF/ANSI 173-2013) includes the following revisions, which allow NSF International increased flexibility in selecting finished product claims for analysis based on the number of finished product claims and ingredients present on the product label.

Issue 47 – Product Requirements

Includes updates to sections 2, 5.1.1, 5.1.2, 5.2.1 and 5.2.2

NSF offers a certification program to this Standard. Products certified by NSF carry the NSF Mark, the leading mark in public health and safety certification around the world. The NSF Mark on a product gives consumers and retailers assurance that the product meets the requirements of the NSF Standard. For more information on the NSF certification program, please contact the General Manager of Dietary Supplements, P.O. Box 130140, Ann Arbor, Michigan 48113-0140 or at 734-769-8010.

Suggestions for improvement of this Standard are welcome. This Standard is maintained on a Continuous Maintenance schedule and can be opened for comment at any time. Comments should be sent to Chair, Joint Committee on Dietary Supplements at standards@nsf.org, or c/o NSF International, Standards Department, P.O. Box 130140, Ann Arbor, Michigan, 48113-0140, USA.

² The information contained in this Foreword is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI's requirements for an ANS. Therefore, this Foreword may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to the Standard.

This page is intentionally left blank.

NSF International Standard for Dietary Supplements —

Dietary supplements

1 General

1.1 Purpose

This Standard provides test methods and evaluation criteria for dietary supplement products to allow for the determination that the ingredients in the product are accurately identified, that the product contains the quantity of dietary ingredients and marker constituents declared on the product label, and that the product does not contain unacceptable quantities of contaminants.

This Standard provides criteria for determining that Good Manufacturing Practices were followed in the production of dietary supplements.

1.2 Scope

This Standard contains requirements for dietary supplements that contain one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients.

Products and ingredients deemed a hazard to public health or safety by a regulatory agency having jurisdiction shall be excluded from the scope of this document. Conventional foods are excluded from the scope of this Standard.

Manufacturers shall exercise due diligence to ensure compliance with all applicable regulatory requirements, but compliance with this Standard in itself does not imply that all regulatory requirements have been met.

1.3 Formulation submission

The manufacturer shall submit, at a minimum, the following information for each product:

- complete formulation information, which includes the following:
 - the composition of the formulation (in percent or parts by weight for each ingredient in the formulation including excipients);

NOTE – Ranges shall be considered acceptable.

- the reaction process, if applicable;
- the raw material ID number (if applicable), chemical/material name, trade name and supplier(s) for each chemical present in the formulation;