



December 5, 2000

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
Room 1-23  
12420 Parklawn Drive  
Rockville, MD 20857

### **Citizen Petition**

#### **I. Action Requested**

The undersigned submits this petition under Sections 403(a), 403(r), 502(f)(1), and 505(a) of the Federal, Food, Drug and Cosmetic Act (FDCA) to request that the Commissioner of the Food and Drug Administration (FDA) take prompt enforcement action against manufacturers and distributors of garlic supplements that are misbranded.

The Center for Science in the Public Interest (CSPI)<sup>1</sup> requests that the FDA order manufacturers and distributors of garlic supplements to halt the use of unapproved health claims and/or false and misleading structure/function claims linking the ingestion of garlic to cholesterol levels, heart disease or cardiovascular health. To facilitate the FDA's review of the products, CSPI is attaching copies of product labels and website materials.<sup>2</sup>

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<sup>1</sup> CSPI is a nonprofit organization based in Washington, D.C. that is supported by over 800,000 members who subscribe to its *Nutrition Action Healthletter*. CSPI has been working to improve the public's health through better nutrition and safer food since 1971.

<sup>2</sup> The products included in this petition were purchased in the Washington, D.C. area and likely represent only a small fraction of the garlic products being marketed nationwide.

## II. Statement of Factual Grounds

Garlic is the fourth most popular dietary supplement in the United States, accounting for \$75.6 million dollars in annual sales in the United States.<sup>3</sup> Typically, labels for garlic supplements state that they are “clinically proven to lower cholesterol.” Claims to lower cholesterol constitute unapproved health claims.<sup>4</sup> In addition, such claims are not supported by scientific evidence and are, therefore, false or misleading.

Some products also claim to “maintain normal blood pressure levels,” “promote healthy circulation” or “support a healthy cardiovascular system.” Although such claims fall into the category of “structure/function claims,” products bearing such claims are misbranded because the statements are false or misleading.

On October 3, 2000, the Agency for Healthcare Research and Quality (AHRQ) of the Department of Health and Human Services released an evidence report concluding that garlic “does not appear to offer long-term protection against cardiovascular disease.”<sup>5</sup> Although the use of garlic may lower low density lipoproteins (LDLs) in the short run, it does not lower cholesterol levels for periods longer than three months.<sup>6</sup> The inability of garlic supplements to reduce cholesterol levels beyond three months is crucial because it is the *prolonged* elevation of

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<sup>3</sup> *Red-Hot Herbal Supplements Cool Off Just a Little*, 17(8) MMR 28 (Mar. 20, 2000).

<sup>4</sup> Food and Drug Administration Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Final Rule, 65 Fed. Reg. 999 (Jan. 6, 1999)[*hereinafter* Final Rule].

<sup>5</sup> AHRQ, *AHRQ Report Finds Little or Inconclusive Evidence of Health*, Press Release (Oct. 3, 2000) at 4-5.

<sup>6</sup> AHRQ, *Garlic Effects on Cardiovascular Risks and Disease, Protective Effects Against Cancer, and Clinical Adverse Effects* (Oct. 2000).

blood cholesterol levels that raises the risk of cardiovascular disease. Thus, a product that does not work beyond three months is virtually useless for controlling cholesterol.<sup>7</sup> The AHRQ report also found no evidence that garlic has a beneficial impact on blood pressure or diabetes.<sup>8</sup> The AHRQ study is the most thorough review of the scientific evidence about the effects of garlic on cardiovascular disease, and includes a new meta-analysis of the long-term impact of garlic on cholesterol levels.

### III. Statement of Legal Grounds

#### A. Some Garlic Products Are Misbranded Because They Make Express, Unapproved Health Claims

Under the Nutrition Labeling and Education Act of 1990 (NLEA) and its implementing regulations, a food or dietary supplement may not make claims to cure, prevent or treat a disease

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<sup>7</sup> Similarly, a meta-analysis of randomized clinical trials by alternative medicine experts at the University of Exeter in England concluded that: “the use of garlic for hypocholesterolemia is . . . of questionable value.” The researchers found that the six best-designed and best-executed studies of garlic supplements failed to show any effect on cholesterol levels. C. Stevinson, M.H. Pittler, *Garlic for treating hypercholesterolemia. A Meta-analysis of randomized critical trials*. 133 (6) *Ann Intern Med* 420-9 (Sept. 19, 2000).

In addition, the German Commission E monograph for the garlic clove no longer lists the cholesterol reduction claim. Personal correspondence between Dr. Werner Busse, a well-known herbal authority in Europe, and David Schardt, CSPI Associate Nutritionist, July 26, 2000. Dr. Busse stated that although there was no public or official statement regarding the change in the type of claims that are permissible for garlic, the change is “evident from the publication of new authorization published in the German Federal Gazette (*Bundesanzeiger*).” *Id.* The German Commission E is an expert committee established in 1978 to evaluate the safety and efficacy of herbs and herb combinations sold in Germany. The Commission’s findings are used throughout the world.

<sup>8</sup>AHRQ Report, *supra* note 5.

unless the claim is approved by the FDA as a “health” claim following a rulemaking proceeding.<sup>9</sup>

The Food and Drug Administration Modernization Act of 1997 (FDAMA) also permits health claims to be based upon an acceptable authoritative statement from government agencies with scientific expertise so long as appropriate notice is provided to the FDA and the FDA does not object within a specified time period.<sup>10</sup>

The FDA has previously determined that claims to lower cholesterol,<sup>11</sup> to promote low blood pressure,<sup>12</sup> and to inhibit platelet aggregation<sup>13</sup> may not be used on supplement labels unless the manufacturer petitions and obtains an authorized health claim or files and obtains a new drug application. Notwithstanding this prohibition, the following products make such claims:

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<sup>9</sup> In response to the court decision in *Pearson v. Shalala*, the FDA has adopted a new enforcement policy for health claims that do not meet the statutory requirements for significant scientific agreement. Rather than denying a petition for a health claim that does not meet this standard, the Agency will permit a petitioner to make a qualified claim so long as health and safety are not threatened, the evidence supporting the claim outweighs the evidence against it, and the claim otherwise meets the general requirements for a health claim. Qualified health claims are not subject to the notice and comment rulemaking requirements that are applicable to health claims that meet the significant scientific agreement standard. Food Labeling; Health Claims and Label Statements for Dietary Supplements; Update to Strategy for Implementation of Pearson Court Decision, 65 Fed. Reg. 59855 (Oct. 6, 2000).

<sup>10</sup> FDCA § 403(r), 21 U.S.C. § 343(r), 21 U.S.C. § 101.70. Although technically, the “authoritative statement” provision in FDAMA is applicable only to foods, the FDA has proposed a rule to allow it to apply equally to dietary supplements. 64 Fed. Reg. 3250 (Jan. 21, 1999).

<sup>11</sup> See note 4, *supra* at 1019.

<sup>12</sup> *Id.* at 1006. High blood pressure is associated with increased risk of heart attack, stroke and kidney disease.

<sup>13</sup> *Id.* at 1016.

- **Kwai Heart Fit Garlic, distributed by Lichtwer Pharma, U.S. Inc.:** “Kwai’s Exclusive Formula is *Proven to Lower Cholesterol* and Maintain a Healthy Heart and Circulatory System;” “Kwai Heart Fit is the advanced, possibly ultimate heart care supplement combining all the *cholesterol lowering* benefits of garlic with antioxidants for heart health.” (emphasis added) (Exhibit 1)
- **Garlic Supplement, distributed by Nature Made Nutritional Products:** “Studies indicate that consumption of garlic may *help lower blood cholesterol levels.*” (emphasis added) (Exhibit 2)
- **Garlic Supplement, distributed by Nature’s Resource Products:** “Scientific studies have shown garlic may help *reduce blood cholesterol.*” (emphasis added) (Exhibit 3)

These supplements are in violation of Sections 403(r)(1)(B) of the FDCA as a misbranded food; section 502(f)(1) as a misbranded drug; and section 505(a) as an unapproved new drug.<sup>14</sup>

#### **B. Some Products Are Misbranded Because They Make Implied, Unapproved Health Claims**

Other claims being made for garlic products constitute implied health claims under the criteria set forth in the implementing regulations to the NLEA. Health claims include any claim that expressly, *or by implication*,<sup>15</sup> characterizes the relationship of any substance to a disease or health-related condition.<sup>16</sup> No such claim may be made in the labeling of a dietary supplement unless the claim is specifically authorized.<sup>17</sup>

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<sup>14</sup> 21 U.S.C. §§ 343(r)(1)(B), 352(f)(1), 355(a).

<sup>15</sup> The Agency defines implied health claims as “statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.” 21 C.F.R. § 101.14(a)(1).

<sup>16</sup> *Id.*

<sup>17</sup> 21 U.S.C. § 343(r), 21 U.S.C. § 403 (r); 21 C.F.R. § 101.14.

To determine whether a claim constitutes an implied health claim, FDA uses a two-step analysis:

- Labeling claims need to be considered in their entirety and *in context* to determine whether the elements of a health claim are present. FDA has therefore revised the definition of an implied health claim. . . to clarify that the claim will be evaluated within the context of the total labeling to determine if an implied health claim has been made.<sup>18</sup>
- “. . . [T]he focus of its determination as to whether a claim is an implied claim should be on what the claim is saying.” The FDA considers both manufacturers’ *intent* and consumer perception to determine what is actually being said.<sup>19</sup>

### 1. “Heart Healthy” Is an Implied Health Claim

The claim “heart healthy,” for example, has been explicitly recognized by the Agency as an implied health claim. As the FDA explained: “[l]abeling that links a specific food to a statement such as ‘Heart Healthy’ contains both the substance element (reference to a specific food) and the disease-condition element (implied reduction in risk of heart disease) of a health claim.”<sup>20</sup>

Under this principle, the following claims constitute unapproved implied health claims:

- **Kyolic Nutritional Supplement, made by Wakunaga of America, Ltd.:** “supports *healthy heart*.” (emphasis added) (Exhibit 4)
- **Your Life Advanced Strength Enteric Coated Garlic, Leiner Health Products, Inc.:** “Clinical research has shown that regular consumption of garlic may help promote

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<sup>18</sup> 58 Fed. Reg. 2,478, 2,483 (Jan. 6, 1993) (emphasis added).

<sup>19</sup> *Id.*

<sup>20</sup> U.S. Dept. of Health and Human Services, Public Health Service, Food and Drug Administration, Questions and Answers, Volume II: A Guide for Restaurants and Other Retail Establishments 22 (1995).

*healthy heart* function and regulate cholesterol levels.” (emphasis added)<sup>21</sup> (Exhibit 5)

## 2. Claims for Serious Health Conditions Beyond the Ability of a Consumer to Evaluate Are Implied Health Claims

According to FDA, “[a] claim promoting ‘use for a serious health condition that is beyond the ability of the consumer to evaluate is simply one form of implied disease claim.’”<sup>22</sup> Claims such as “garlic will keep a heart healthy” or “maintain a healthy cardiovascular system” are examples of such claims. The following statements also constitute claims that are beyond the ability of the consumer to evaluate:

- **Super Garlic, distributed by Schiff Products, Inc.:** “*helps maintain healthy cholesterol, triglycerides and LDL cholesterol levels,*”<sup>23</sup> “Long term use of garlic oil supports normal platelet function.” (emphasis added) (Exhibit 6)
- **Daily garlic, distributed by Rite Aid Corp.:** “Research indicates that consumption of garlic helps *regulate cholesterol levels,*<sup>24</sup> as well as maintain *normal blood pressure levels.*<sup>25</sup> Scientific studies suggest that the frequent inclusion of garlic in the diet may offer another means to help maintain health.” (Exhibit 7)

## 3. Blood Pressure Claims Are Implied Health Claims

The FDA has stated that “there may be cases . . . in which a statement of health

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<sup>21</sup> *But see*, Final Rule, *supra* note 4 at 1021. In attempting to draw a line between permissible structure/function claims and impermissible disease claims for dietary supplements, the FDA stated that product names could include “Heart Healthy.” *Id.* at 1021.

<sup>22</sup> *Id.* at 1018. (Emphasis added).

<sup>23</sup> The FDA has stated that use of the term “healthy cholesterol” may be misleading to consumers because they associate the term with high density lipoproteins (HDL) which are believed to be beneficial. Final Rule at 1019.

<sup>24</sup> Regulate is defined as “to fix or adjust.” Webster’s New World Collegiate Dictionary, (1977). Only health care professionals have the ability to evaluate and regulate cholesterol levels through appropriate medical intervention.

<sup>25</sup> (Emphasis added.)

maintenance can be understood only as a claim of prevention of a specific disease, in which case it will be considered a disease claim.”<sup>26</sup> The agency stated that it “agrees that claims that refer to synonyms for disease, direct manifestations of disease, and surrogates for disease are disease claims.”<sup>27</sup> Blood pressure claims, such as “maintain normal blood pressure levels” as used for the Rite Aid product satisfy these criteria.

Consumers are concerned about preventing and treating high blood pressure because hypertension, which in itself is a disease, is also associated with heart disease and stroke. Thus, structure/function claims for maintaining blood pressure are actually implied health claims.

#### **4. Some Products Are Misbranded Because the Manufacturers’ Intent Demonstrates that the Claims Are Implied Health Claims**

Under the definition of a drug found in the FDCA, “intent” is key in determining whether a product is, in fact, a drug.<sup>28</sup> “It is well established that the ‘intended use’ of a product, within the meaning of the Act, is determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant source . . .”<sup>29</sup> As the court explained in *Hanson v. Schuster*:

Countless court decisions emphasize that it is the *intended use* of an article which determines whether or not it is a “drug,” and that even the most commonly ingested foods and liquids are ‘drugs’ within the meaning of the Act if the intended use of such articles when distributed in interstate commerce falls within the definition of § 321(g)(1). . . .<sup>30</sup>

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<sup>26</sup> *Id.*

<sup>27</sup> *Id.* at 1015.

<sup>28</sup> FDCA § 201(g), 21 U.S.C. § 321(g). “The term ‘drug’ means: articles *intended* for use in the diagnosis, cure, mitigation, treatment or prevention of disease. . . .” *Id.* (Emphasis added).

<sup>29</sup> *Hanson and Shuster v. U.S.*, 417 F. Supp. 30, 35 (D. Minn.), *aff’d* 540 F.2d 947 (8th Cir. 1976).

<sup>30</sup> *Id.* at 34-35.

Use of the phrase “regulate cholesterol” in the following labels indicates that the products are intended to adjust cholesterol levels rather than maintain already normal levels.<sup>31</sup>

- **Daily Garlic, distributed by Rite Aid Corp.:** “Research indicates that consumption of garlic helps *regulate* cholesterol levels.” (emphasis added) (Exhibit 7)
- **Your Life Advanced Strength Enteric Coated Garlic, Leiner Health Products, Inc.:** “Clinical research has shown that regular consumption of garlic may help promote healthy heart function and *regulate* cholesterol levels.” (emphasis added) (Exhibit 5)

In determining a manufacturer’s intent, advertising--including claims on Internet sites-- can be taken into account.<sup>32</sup> The following claims which have appeared on the Internet demonstrate the requisite intent for a drug claim:

- **Nature Made:** “Scientific studies have shown that Garlic *may help reduce blood cholesterol.*”<sup>33</sup> (Exhibit 8)
- **Lichtwer Pharma U.S., Inc. (Kwai)** “. . . Kwai is a great place to start because it is *proven to lower cholesterol....* [R]ecently conducted tests, featured in the American Heart Associations’s journal *Circulation*, have shown that Kwai also *hinders stiffening of the aorta--*<sup>34</sup> the main artery that carries blood from the heart to the rest of the body. With better aorta elasticity, the heart does not have to work as hard to pump blood.”<sup>35</sup> (Exhibit 9)
- **Kyolic:** The website includes a Scientific Literature Review of Aged Garlic Extract. The headings for the reviews are as follows: “May Afford Protection Against Occlusive

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<sup>31</sup> See note 24, *supra*.

<sup>32</sup> Letter from James A. Rahto, Director, Minneapolis District, FDA, to Terrence J. Lemerond, President, Enzymatic Therapy, Inc. (May 5, 2000).

<sup>33</sup> Nature Made Website <<http://www.naturemade.com/inside/products/garlicclove.html>> (visited Sept. 22, 2000).

<sup>34</sup> FDA has defined disease as: “damage to an organ, part, structure or system of the body.” 21 C.F.R. § 101.93g(1). Hindering damage to the aorta is certainly a disease claim.

<sup>35</sup> Lichtwer Pharma U.S., Inc. <<http://www.lichtwer.com/kwai/index.html>> (visited Oct. 10, 2000).

Cardiovascular Malfunction via Anti-lipid, Anti-clotting and Other Properties; May Afford Protection Against Cancer and Function as an Adjuvant to Cancer Therapy; May Enhance Immune Function and Provide Anti-Infection Support.”<sup>36</sup> (Exhibit 10)

- **Sunsource (Garlique):** “A healthy heart.”<sup>37</sup> (Exhibit 11)

### **C. The Products are Misbranded Because they Make False or Misleading Claims**

Regardless of how the claims are characterized, the claims are false and misleading because they contradict the findings of the AHRQ report.

“Any single false, misleading, *exaggerated, ambiguous or over-emphasized* statement or representation in the labeling of a drug or a food misbrands the articles within the meaning of 21 U.S.C. [sic] 343(a) or § 352(a).”<sup>38</sup> To determine whether labeling is false or misleading, a key question is whether the product claims can be proven. “The susceptibility of effectiveness to proof as a fact necessarily determines whether assertions can be judged false or misleading.”<sup>39</sup>

As AHRQ stated, garlic “does not appear to offer long-term protection against cardiovascular

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<sup>36</sup> Kyolic website <<http://www.kyolic.co/inf3.htm>> (visited Oct. 10, 2000).

<sup>37</sup> Sunsource <<http://clients.3hdcom/recover/products/garlique.html>> (visited Oct. 10, 2000).

<sup>38</sup> U.S. v. An Undetermined Number of Shipping Packages . . . Labeled in Part . . . “Vitasafe Formula M,” 226 F. Supp. 266, 278 (D. N.J. 1964); remanded on other grounds, 345 F.2d 864 (3d Cir. 1965), *cert. denied*, (Nov. 15, 1965), 382 U.S. 918 (emphasis added).

<sup>39</sup> U.S. v. 7 Jugs, Etc. of Dr. Salsbury’s Rakos, 53 F. Supp. 746, 758 (D.Minn. 1944). Cases involving claims for medical devices are also analogous. E.g., *United States v. 6 Devices, “Electreat Mechanical Heart,”* 38 F. Supp. 236 (W.D. Mo. 1941) (Labeling for a flashlight-like device that allegedly produced an electric current that would “relieve pain, strengthen weak eyes . . . thicken thin lips . . . cure lumbago . . .” was held to be false and misleading. In explaining its decision, the court said “in each instance the explanation of why the instrument could not produce the results claimed for it was most convincing . . . From a practical standpoint, the benefit to be derived . . . [was] that the use of the instrument would not injure one if there was nothing the matter with him, but that if the person was suffering from any disorder or ailment its use might and probably would be injurious.”) *Id.* at 6-7.

disease.” The claims thus constitute misbranding.<sup>40</sup>

#### **D. Other Products are Misbranded Because they Make False and Misleading Structure/Function Claims**

The Dietary Supplement Health and Education Act permits dietary supplements to make claims to affect a structure or a function of the body (structure/function claims) without prior authorization so long as the product does not claim to “diagnose, treat, cure or prevent” a disease. Manufacturers, however, must have substantiation for the claims being made and such claims should not be false or misleading.<sup>41</sup>

The following products are misbranded because they make structure/function claims that are unsubstantiated and/or false and misleading in light of the AHRQ report.<sup>42</sup>

- **Garlinase 4000, distributed by Enzymatic Therapy:** “Nutritionally supports healthy cholesterol levels”; “4,000 mg of fresh garlic *based on the German Commission E*

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<sup>40</sup> Cf. *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), 164 F.3d 650 (D.C. Cir. 1999), *rehearing en banc denied*, 172 F.3d 72 (1999). The *Pearson* court concluded that, in some instances, a disclosure statement characterizing the level of scientific support is an appropriate way to remedy a misleading impression created by a claim. However, the court did *not* conclude that disclosures are adequate in all situations. As the court stated: “Nor do we rule out the possibility that where evidence in support of a claim is outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban it outright.” *Id.* at 659. The court stated further: “Similarly, we see no problem with the FDA imposing an outright ban on a claim where evidence in support of the claim is qualitatively weaker than evidence against the claim.” *Id.* at n.10.

<sup>41</sup> FDCA § 403(r)(6), 21 U.S.C. § 343(r)(6). The FDA has not yet established substantiation requirements for structure/function claims. The FDA, however, has stated that the fact that it may be difficult to substantiate claims “does not alter the terms of the statute. Manufacturers are responsible for determining whether claims for their products can be appropriately substantiated, and to use only those claims for which they have substantiation.” 65 Fed. Reg. 999, 1012 (Jan. 6, 2000) (Final rule on structure/function claims). Substantiation does not exist for the claims mentioned in this petition.

<sup>42</sup> See discussion in Section II, *supra*.

monograph.”<sup>43</sup> (emphasis added) (Exhibit 12)

- **Kwai Heart Fit Garlic, distributed by Lichtwer Pharma, U.S. Inc. :** “The Clinically Proven Formula with Antioxidants A, C & E for A Healthier Circulatory System,” “Kwai’s Exclusive Formula is *Proven* to. . . Maintain a Healthy Heart and Circulatory System;” “*Only Kwai’s exclusive garlic formula is proven in over 30 clinical studies.*” (emphasis added) (Exhibit 1)
- **Super Garlic, distributed by Schiff Products, Inc.:** “supports cardiovascular well-being,” “supports a healthy cardiovascular system, helps maintain healthy cholesterol, triglycerides and LDL cholesterol levels;” “Long term use of garlic oil supports normal platelet function.” (Exhibit 6)
- **Garlic XTRA, distributed by Sundown Herbals:** “promotes healthy heart function and cholesterol levels”; “[ingredients] work in harmony to help promote healthy heart function and cholesterol levels”; “[garlic] has been shown to help promote healthy cholesterol levels, cardiovascular health, and circulatory function.” (emphasis added) (Exhibit 13)
- **Garlique, distributed by Chattem, Inc.:** “supports cardiovascular health,” “Garlic contains the chemicals alliin and allinase. These two chemicals combine to produce allicin -- the active ingredient in garlic which *most scientists believe* is responsible for providing this important support for cardiovascular health.” (emphasis added) (Exhibit 14)
- **Kyolic Nutritional Supplement, made by Wakunaga of America Co. Ltd.:** “*Scientifically proven effective,*” “supports healthy heart and overall function.” (Exhibit 4)
- **One A Day Dietary Supplement, distributed by Bayer Corp.:** “Helps maintain healthy cholesterol levels.”<sup>44</sup> (Exhibit 15)
- **Your Life Advanced Strength Enteric Coated Garlic, Leiner Health Products, Inc.:** “Helps maintain healthy heart function and regulate cholesterol,” “*Clinical research has shown* that regular consumption of garlic may help promote healthy heart function and regulate cholesterol levels.”(emphasis added) (Exhibit 5)

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<sup>43</sup> As discussed in note 7, *supra*, German Commission E no longer supports this use.

<sup>44</sup> The FDA has stated that references to healthy cholesterol levels are misleading to consumers. See note 4, *supra* at 1019.

- **GarliPure, Natrol, Inc.:** “Helps maintain a healthy cholesterol level.” (Exhibit 16)
- **Daily garlic, distributed by Rite Aid Corp.:** “*Research indicates* that consumption of garlic helps. . .maintain normal blood pressure levels. *Scientific studies suggest* that the frequent inclusion of garlic in the diet may offer another means to help maintain health.” (emphasis added) (Exhibit 7)

#### **IV. Conclusion**

Given the widespread use of garlic supplements and the proliferation of false or misleading claims, we believe the FDA should take prompt enforcement action to protect consumers. Failure to act will mean that millions of consumers may be relying on an ineffective and inappropriate treatment for serious health conditions that, if not properly treated, can lead to death.

#### **V. Environmental Impact**

This petition is subject to a categorical exclusion under 21 C.F.R. § 25.30(b) and, therefore, CSPI is not required to prepare an environmental assessment.

#### **V. Economic Impact**

No statement of economic impact is required at this time.

#### **VII. Certification**

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

Bruce Silverglade  
Director of Legal Affairs

  
Ilene Ringel Heller  
Senior Staff Attorney

Attachments

The Proven Cholesterol Lowering Formula With Antioxidant Protection.\*

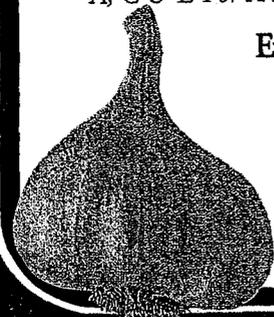


100% SATISFACTION GUARANTEED

# Kwai® Heart Fit™ Garlic

The Clinically Proven Formula With Antioxidants A, C & E For A Healthier Circulatory System.\*

Exclusive LI 111™ Formula



Dietary Supplement  
**30 TABLETS**  
Standardized and Tested

**Lichtwer Pharma**

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

# Kwai® Heart Fit™ Garlic



† Based on Pharmacy Times survey of 1,000 pharmacists.

Learn More About Kwai® Heart Fit™ and Our Other Clinically Proven Herbal Supplements at [www.lichtwer.com](http://www.lichtwer.com).



100% SATISFACTION GUARANTEED

## Kwai's Exclusive Formula Is Proven To Lower Cholesterol and Maintain A Healthy Heart and Circulatory System.\*

- Kwai Heart Fit is the advanced, possibly ultimate heart care supplement combining all the cholesterol lowering benefits of garlic with antioxidants for heart health.\*
- Because each tablet of Kwai Heart Fit has 300mg of garlic, you need only take 1 tablet, 2 times per day with meals to benefit from the cholesterol lowering capability of Kwai's clinically proven formula.\*
- The antioxidants A, C and E provide extra support for your heart and circulatory system.\*
- Only Kwai's exclusive garlic formula is proven in over 30 human clinical studies.

**Ingredients:** Garlic powder (clove), sucrose, ascorbic acid, sorbitol, a-tocopherol acetate, talc (natural tableting aid), corn starch, hydroxy propylmethyl

cellulose, polyvinylpyrrolidone (pvp), silicon dioxide, vitamin A acetate, stearic acid, castor oil, magnesium stearate, powdered cellulose, glucose syrup, titanium dioxide (mineral-based whitening pigment), carnauba wax/bees wax, riboflavin, b-carotene

Cholesterol lowering results observed after 12 weeks of usage.

**Lichtwer Pharma**

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Caution: Blister pack ensures product freshness, safety, and convenience. Do not use if seal or blister is broken. Keep in a cool, dry place out of reach of children. If you are under treatment for a blood disorder or have a disease or health related condition that requires the lowering of cholesterol, consult a health professional before taking Kwai.

The LI 111 garlic powder used in Kwai undergoes analytical testing to standardize the allicin yield. The tablet coating ensures the freshness and intensity of the garlic components and delivers an odor free product.

**Suggested Serving:** Take 1 tablet, 2 times daily with water, ideally with meals. Do not chew, but swallow whole to ensure maximum breath freshness.

**Guaranteed Odor Free:** Kwai's special scientific coating protects the concentrated garlic and releases it well down the digestive tract to prevent any odor, as long as tablet is not broken or chewed before swallowing. In the event you are not satisfied, a full refund of your purchase price will be made if you send the unused portion and your receipt to the name and address below. Only one refund per household is allowed. Kwai Guarantee: Lichtwer Pharma, 2 Industrial Way West, Eatontown, NJ 07724

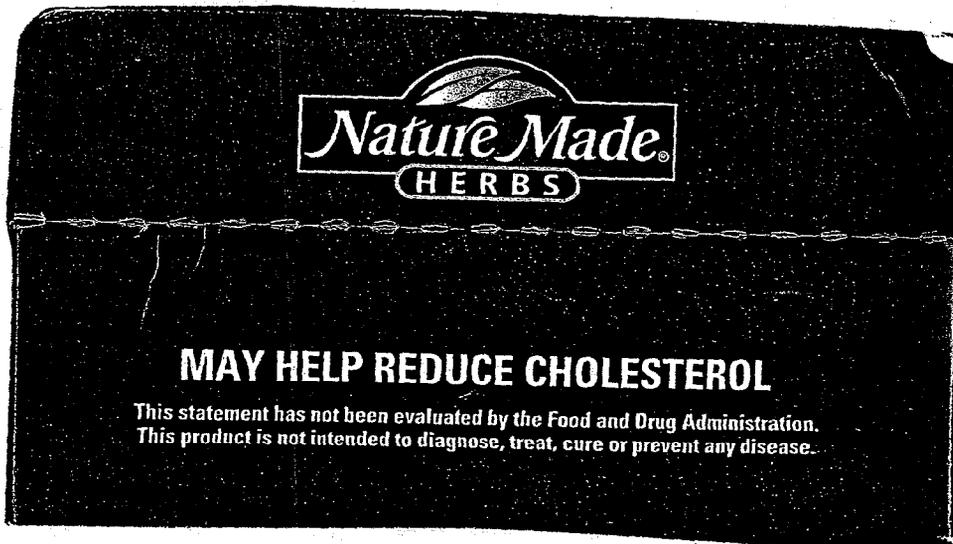
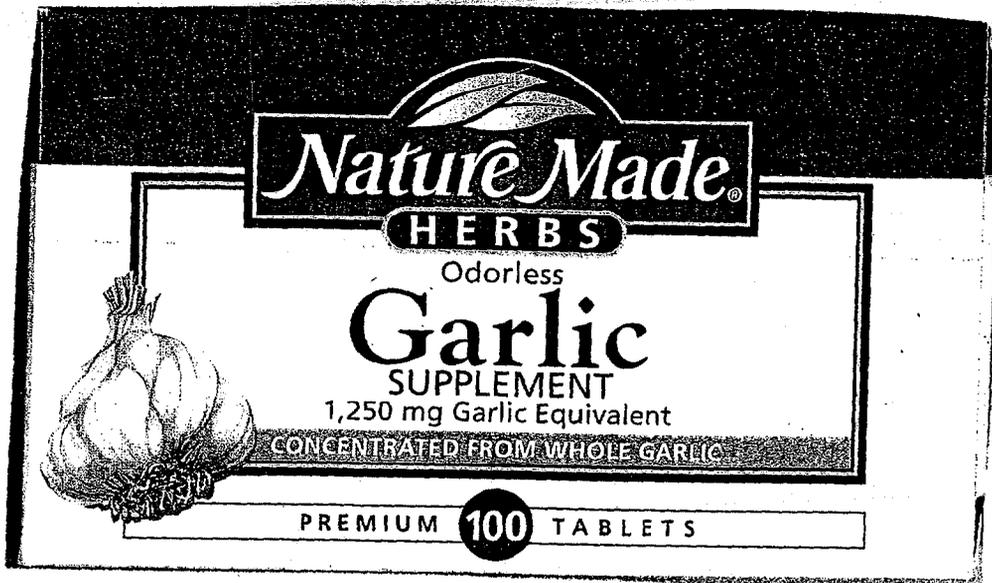
### Supplement Facts

Serving Size 1 Tablet  
Servings Per Package: 30

Amount Per Tablet	% Daily Value
Vitamin A	5,280 IU 53%
Vitamin C	160 mg 133%
Vitamin E	40 IU 67%

Garlic Powder (clove) 600mg\*  
(Allium sativum L.)

\*Daily Value Not Established



## Odorless Garlic

Studies indicate that consumption of garlic may help lower blood cholesterol levels.† Nature Made Garlic is quick-cool dried to preserve the many natural components of garlic. Nothing is added or extracted from raw garlic except the moisture. This special process yields a mild yet potent garlic product with a pleasant garlic scent. The gentle release of garlic in the body results in virtually no after odor on the breath or skin, when taken according to suggested directions.

**No Artificial Colors • No Artificial Flavors • No Preservatives  
No Chemical Solvents, Starch or Gluten**

**Suggested Use:** Take one tablet two times daily with a meal. To ensure breath freshness, do not chew tablet. Store in a cool, dry place, out of reach of children.

### Supplement Facts

Serving Size 1 tablet

#### Amount Per Tablet

Concentrated Garlic bulb	500 mg*
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\*Daily Value not established.

**Do not use if tamper evident printed foil seal over tablets is broken.**

Each tablet contains 500 mg concentrated garlic, the equivalent of 1,250 mg garlic bulb. Two tablets equal 2,500 mg, or one clove of garlic, a commonly suggested daily dosage of garlic. Each tablet is coated for easy swallowing.

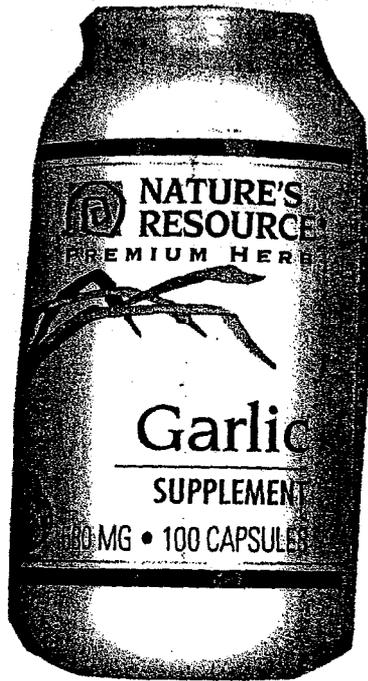
**OTHER INGREDIENTS:** Cellulose, Croscarmellose Sodium, Hydroxypropyl Methylcellulose, Magnesium Stearate, Polyethylene Glycol, Carnauba Wax.

Distributed by: **Nature Made Nutritional Products**, Mission Hills, CA 91346-9606, U.S.A.

1-800-276-2878 • [www.naturemade.com](http://www.naturemade.com)

Odorless Garlic tablets made to Nature Made's guaranteed purity and potency standards.

†This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.



Select California Grown  
GARLIC BULB  
No artificial colors, flavors or preservatives.  
Scientific studies have shown Garlic helps help reduce blood cholesterol. Nature's Resource® Garlic has been processed to preserve the sulfur compounds in the bulb. These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, cure or prevent any disease.

Supplement Facts	
Serving Size 1 capsule	
Amount Per Capsule	
Garlic bulb	100 mg
Allicin	1.2 mg
*Daily Value not established	

Other Ingredients: Gelatin, Water, Sodium Lauryl Sulfate, Silicon Dioxide  
©1999 Dist. by Nature's Resource  
Mission Hills, CA 91346-9606  
1-800-314-HERB • www.naturesresource.com

Recommendation: As an addition to a healthy diet, take one capsule three times daily with water at mealtimes.  
Keep out of reach of children.  
Color variation is normal in this product.  
Double safety sealed with a primary shrinkwrap film and a primary freshness seal.  
DO NOT USE IF EITHER SEAL IS BROKEN OR MISSING.



LIST NO. 14018 CAT. NO. 5400  
128AA

**NUTRITIONAL SUPPLEMENT**  
**KYOLIC®**  
**Liquid**  
*Aged Garlic Extract™*



NET 2 FL. OZ. (60ML)

**SUGGESTED USE:** Simply take 1/2 teaspoon or put in your favorite beverage twice daily. People all over the world take Liquid Aged Garlic Extract for its convenience and its organic goodness. Worldwide, the preferred form of garlic. Taste the benefits daily.

Supplement Facts		
Serving Size 1 ml	Amount per Serving	% Daily Value
Kyolic® Aged Garlic Extract**†	1 ml	*
† Special Garlic Preparation. *Daily Value not established		
† Contains water and residual alcohol from extraction.		

Keep in a cool, dry place with cap tight.  
 (Refrigeration is recommended after first use.)

Manufactured and distributed by:  
 Wakunaga of America Co., Ltd.  
 Mission Viejo, CA 92691 U.S.A.

Lot No. 8J06C  
 Exp. Date: 03.2002 L100A26E

**SUPPORTS HEALTHY HEART AND OVERALL FUNCTION\*\***

**KYOLIC®**  
 NUTRITIONAL SUPPLEMENT

*100% Organically Grown Garlic*

*The ONLY antioxidant garlic supplement*

*Scientifically Proven Effective*

*The one and only aged garlic liquid extract*

*No Garlic Odor*

NET 2 FL. OZ. (60ML)

**Aged Garlic Extract™**

**YourLife**

Call us 1-800-533-VITA

**Circulatory or Heart**  
Helps Maintain  
Healthy Heart Function  
& Regulate Cholesterol\*



# Advanced Strength Enteric Coated Garlic

650 mg

Standardized to 6500 mcg allicin per caplet

Dietary Supplement

60 Caplets

\*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

## Supplements



Servin

Each Caplet Contains

% Daily Value

Garlic Powder (*Allium sativum*) (clove) 650 mg \*\*  
(Standardized to 1% Allicin)

\*\*Daily Value (DV) not established.

**INGREDIENTS:** Garlic Powder, Cellulose, Cellulose Acetate Phthalate, Croscarmellose Sodium, Stearic Acid, Pluronic Poloxamer, Diethyl Phthalate, Silicon Dioxide, Magnesium Stearate, Pharmaceutical Glaze, Hydroxypropyl Methylcellulose, Hydroxypropyl Cellulose, Polysorbate 80, Polyethylene Glycol 3350.

©Your Life, a registered trademark of Leiner Health Products, Inc., Carson, California 90745 U.S.A.

[WWW.YOURLIFEVITAMINS.COM](http://WWW.YOURLIFEVITAMINS.COM)

Clinical research has shown that regular consumption of garlic may help promote healthy heart function and regulate cholesterol levels.\* Your Life® Advanced Strength Enteric Coated Garlic is a standardized garlic supplement that has been specially formulated to be:

- The Highest Potency available for "Once-A-Day" dosage.
- Virtually Odor-Free

Enteric Coated Benefits:

- May help the Garlic to fully absorb in the intestine where the beneficial ingredients in garlic can best help regulate heart health.\*
- May help protect the allicin content and other beneficial sulphur compounds found in garlic from acid degradation in the stomach.
- It may also minimize gastric upset in those with sensitive systems.

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Suggested use: Take one caplet daily, with a meal.

Keep out of the reach of children.  
Keep in a cool dry place.

YC6575Q08



0 74970 06575 8

Garlic when crushed and cooked, forms dialk(enyl) sulfides. Long-term use of garlic oil (aka, dialk(enyl) sulfides) supports a healthy cardiovascular system, helps maintain healthy cholesterol, triglycerides and LDL cholesterol levels. Long-term use of garlic oil supports normal platelet function.\*

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

**GUARANTEED:** No sugar (sucrose, fructose, lactose) salt (sodium chloride), yeast, wheat, gluten or milk. No preservatives, artificial colors or artificial flavors.

**UNCONDITIONALLY GUARANTEED** for purity, freshness and labeled potency.

**KEEP OUT OF REACH OF CHILDREN.**  
STORE IN A COOL, DRY PLACE WITH LID TIGHTLY CLOSED.

# Super Garlic

Supports Cardiovascular Well-being ☆  
Dietary Supplement

**Schiff®**

100 SOFTGELS



Directions: As a dietary supplement, take one (1) softgel daily.

Supplement Facts	
Serving Size One (1) Softgel	
Amount Per Serving	
Dialk(enyl) Sulfides (from garlic oil) (Allium sativum) (tab.)	15 mg*
* Daily value (not established)	

Other ingredients: Soy vegetable oil capsule (pectin and glycerin).

10818



486108181

Distributed by Schiff Products, Inc.  
Salt Lake City, UT, USA 84105  
For information, call:  
1-800-528-6251 (8am-5pm MST)

MN2879B  
EXP 07/02



NEW SIZE

# daily garlic

once-a-day

Odor Free Dietary Supplement

30 tablets

Keeps cholesterol levels in check. Helps maintain normal blood pressure levels. Scientific studies suggest that the frequent inclusion of garlic in the diet may offer another means to help maintain health.



592809

EAG

Conforms to USP <2091> for weight.  
Meets USP <2040> disintegration.

### Supplement Facts

Serving Size 1 Tablet

Each Tablet Contains

Garlic (bulbs) 400 mg\*

\*Daily Value not established.

**OTHER INGREDIENTS:** Dicalcium Phosphate, Stearic Acid, Croscarmallose Sodium, Magnesium Stearate.

Distributed by: Rite Aid Corporation, Harrisburg, PA 17105

**SUGGESTED USE:** Take one tablet each day, preferably after a meal.

Keep out of the reach of children.

Keep in a cool, dry place.

No Preservatives Added

No Artificial Flavors

No Artificial Colors

Rite Aid Daily Garlic offers the benefits of garlic concentrated into a single dose. The special coating process makes the tablets easy to swallow and there is virtually no odor. Research indicates that consumption of garlic helps regulate cholesterol levels, as well as maintain normal blood pressure levels. Scientific studies suggest that the frequent inclusion of garlic in the diet may offer another means to help maintain health.

+ These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

When Alliin and Allinase found in garlic combine in the body, Allicin is produced. The potency of garlic is measured in terms of the Total Allicin Potential™ or TAP™. Each Rite Aid Daily Garlic tablet provides 400 mg of Total Allicin Potential™ Garlic equivalent to 1200 mg of fresh garlic.




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## Garlic Clove - *Allium sativum*

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### What is garlic?

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- Garlic consists of the fresh or dried bulbs, which comprise the main bulb with several secondary bulbs (cloves), of *Allium sativum* L. [Fam. Liliaceae].
- Garlic contains alliin, its degradation products, and sulfur-containing essential oil.
- Other constituents include vitamins A, B, C, and F, adenosine, phytosterols, flavonoids, lipids, proteins, and amino acids.

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### Use?

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**Benefits:** Scientific studies have shown that Garlic may help reduce blood cholesterol.\* Millions of adults around the world enjoy the health benefits of a daily garlic regimen.

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### How much do I need?

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How are you taking this herb?  
 Unless otherwise recommended:  
 Average daily dosage:

- 4g. fresh garlic; equivalent preparations.
- Preparations equivalent to 4 to 12mg. of alliin (approx. 2 to 5mg. of allicin); fully dried powder.
- Dried bulb: 2 to 4g. three times daily.

---

### Is it safe?

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What side effects or adverse reactions are you aware of?

- Gastrointestinal symptoms (rare)
- Changes to the flora of the intestine (rare)
- Allergic reactions (rare)

It can also cause:

**Note:** Garlic's odor may pervade the breath and skin

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### Is there any time when I shouldn't take it?

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Contraindications

- Pregnant or breastfeeding patients should check with their doctors before taking this herb.

- May interfere with existing hypoglycemic and anti-coagulant therapies (e.g. warfarin).
- May potentiate the anti-thrombotic effects of anti-inflammatory drugs.
- May be synergistic with EPA in fish oils.
- May cause experience gastrointestinal irritation when eaten raw (especially if the person is not used to eating raw garlic).
- May cause miscarriage.
- May affect the menstrual cycle.
- May be uteroactive.

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### What foods are good sources?

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Garlic cloves.

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[◀ RETURN TO TABLE OF CONTENTS](#)

**Lichtwer Pharma U.S., Inc.** Home

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**Kwai** Proven Plant Science

**Can Kwai Lower My Cholesterol?**  
 By making smart decisions today, you can help yourself lead a healthier life, and Kwai is a great place to start because it is proven to lower cholesterol.

And that's not all...recently conducted tests, featured in the American Heart Association's journal *Circulation*, have shown that Kwai also hinders stiffening of the aorta — the main artery that carries blood from the heart to the rest of the body. With better aorta elasticity, the heart does not have to work as hard to pump blood. Kwai is a natural step toward leading a healthier life.



- Kwai: Proven to Lower Cholesterol
- Recent Medical Research Shows Kwai Can Help Lower Cholesterol

**The Proven Formulation That's Proven to Work.**

With many choices available in garlic supplements, it's difficult to choose the right one. But the best choice is always a supplement that's standardized and odor-free. That's why it's important to choose the one that's clinically proven to work.

In study after study, Kwai has been shown to lower cholesterol. What's more, these studies have been published in the foremost medical journals. And because our research and clinical trials are so extensive, many other brands of garlic supplements are turning to Kwai's research to support their own claims.

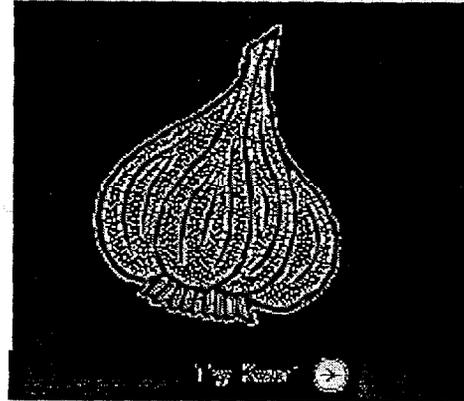
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The statements presented here have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure or prevent any disease. Lichtwer Pharma affirms that the statements presented at this site are supported and controlled clinical and scientific studies.

Lichtwer Pharma U.S., Inc.

**Kwai and Cholesterol****Proven Plant Science****Has Kwai Garlic Been Proven To Be Effective In Lowering Cholesterol?**

Although garlic has been used for countless generations, it's only recently that the beneficial effects of lowering cholesterol have been proven in clinical studies. And Lichtwer Pharma has been at the forefront in the research of garlic supplements since 1981.



When we tested Kwai on real people, we knew that we could achieve real proof of our claims. One of the many clinical trials was conducted in tandem with the Tulane University School of Medicine — and the results showed an average cholesterol decrease of 10 - 15%! Other studies using Kwai support cholesterol decreases of up to 25%.

**What Other Health Benefits Does Kwai Provide?**

As mentioned in *Circulation*, physicians have found that men and women who regularly took Kwai had substantially better aortic elasticity than those who did not. The overall result showed that an increase in stiffness of the aorta can be retarded by the regular intake of Kwai. Kwai is a natural step toward leading a healthier life.

What's more, in our extensive testing Kwai has been found to have no adverse effects. And in long-term treatment, Kwai has been proven both safe and effective.

[Kwai Home](#) [What is Kwai?](#) [Kwai and Cholesterol](#) [Learn More](#) [Contact Us](#)

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# KYOLIC *Information*

Volume 3

## SCIENTIFIC LITERATURE REVIEW OF AGED GARLIC EXTRACT: PHARMACOLOGICAL ASPECTS

Aged garlic extract is a form of garlic produced from a unique aging process. During aging (up to 20 months), unstable, harsh and highly odorous compounds in fresh garlic are converted into more stable, beneficial, safe and much less odorous compounds. The garlic used in aged garlic extract is also organically grown so that it is free of pesticides and herbicides. Various studies have suggested that supplementing one's diet with aged garlic extract may be beneficial. Some promising data includes reports that aged garlic extract:

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### MAY AFFORD PROTECTION AGAINST OCCLUSIVE CARDIOVASCULAR MALFUNCTION VIA ANTI-LIPID, ANTI-CLOTTING AND OTHER PROPERTIES

Various studies have suggested that aged garlic extract and its active compounds may inhibit the synthesis of fatty acids and cholesterol in cultured hepatocytes (liver cells) (1,2), and may reduce total cholesterol, triglycerides and LDL-cholesterol levels in hyperlipidemic humans with an improvement or no effect on HDL-cholesterol (3-6). Research has shown that aged garlic extract may reduce total serum cholesterol and LDL cholesterol in chickens (7-9) to a greater extent than either garlic powders or garlic oil (9). Aged garlic extract also appeared to inhibit platelet aggregation and adhesion (5,8,10) and to inhibit smooth muscle cell proliferation (11). Research has also suggested that aged garlic extract may enhance peripheral blood circulation (12,13).

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### MAY AFFORD PROTECTION AGAINST CANCER AND FUNCTION AS AN ADJUVANT TO CANCER THERAPY

Various cell culture studies have suggested that aged garlic extract and its constituents may inhibit the growth of human breast cancer cells (14,15), several human melanoma cells (31,32), and neuroblastoma cells (33). Various animal studies have suggested that aged garlic extract may inhibit the growth of breast cancer (16-27), bladder cancer (28-30), skin cancer (34-37), colon cancer (41-43), the development of esophageal tumors (44) and stomach and lung tumors (45-47). Studies have suggested that the possible anti-carcinogenic effects of aged garlic extract and its constituents may be due to their ability to reduce the rate of activation of chemical carcinogens (15-22,24-25,38,40-42), to enhance the rate of chemical carcinogen excretion (38), to protect DNA from carcinogen-DNA adduct formation (16-24,39), to enhance enzymes that detoxify carcinogens (14,15,25,39,41-43), and to suppress tumor

cell growth through stimulation of immunoresponder cells (28-30,53-55).

Studies have also suggested that aged garlic extract may be a promising adjuvant to cancer therapy in that it has been shown to reduce side effects such as fatigue and anorexia in head and neck tumor patients on radio- and chemotherapy (48) and to reduce the cardiotoxicity of the potent anti-cancer drug Doxorubicin (49,50).

Aged garlic extract has been and is still being extensively researched by the National Cancer Institute. The following table provides a summary of various cancer studies presented in peer reviewed journals using aged garlic extract and constituents it contains:

#### Inhibition of cancer growth by aged garlic extract

Cancer	<i>In vivo</i> (Animal Model)	<i>In vitro</i> (Test Tube Model)
Bladder	Mice(28-30)	
Breast	Rats(16-25), Dogs(26,27)	Human(14,15)
Colon	Mice(41-43)	
Esophagus	Rats(44)	
Liver		Rat(38-40)
Lung	Mice(45-47)	
Melanoma		Human(31,32), Murine(32)
Neuroblastoma		Human(33)
Skin	Mice(34-37)	
Stomach	Mice(45-47)	

## MAY ENHANCE IMMUNE FUNCTION AND PROVIDE ANTI-INFECTION SUPPORT

Studies have suggested that aged garlic extract mitigates infectious diseases through enhancement of the immune system. Specifically, aged garlic extract appears to enhance natural killer cell activity (51,52), improve helper/suppressor T cell ratios (51,53), stimulate phagocytic activity of macrophages (28,29,38,53-55), and enhance the cytotoxicity of human peripheral blood lymphocytes against tumor cells (56). Aged garlic extract was also found to minimize the immunosuppression induced by UVB radiation (35,37). In one study where mice were pernasally inoculated with influenza virus (AO/PR 8), aged garlic extract was found to enhance the preventative effect of an influenza vaccine and when used alone was found to be as effective as the vaccine (57). Studies have also suggested that aged garlic extract and its constituents may inhibit the growth of *Candida albicans* both *in vitro* (58) and *in vivo* (38,51). It has been shown to hasten the systemic removal of these cells from mice (38) and to improve symptoms of candidiasis (systemic *Candida*) from AIDS patients (51).

## MAY AFFORD LIVER PROTECTION AND DETOXIFICATION

Animal studies have suggested that aged garlic extract and its active compounds may protect the liver from the toxicity of carbon tetrachloride (59,60). In addition, aged garlic extract may increase the glutathione level and glutathione related enzymes which aid in detoxifying the body (14,15,25,39,41-43). Research has also suggested that aged garlic extract may help to protect the body from heavy metal poisoning (54). When aged garlic extract was combined with red blood cells it

prevented lead, mercury and aluminum from destroying them. When no aged garlic extract was added to the blood samples, these heavy metals ruptured the red blood cells.

---

## **MAY PROMOTE GENERAL HEALTH AND ENHANCE ENERGY LEVELS**

Several studies have suggested that aged garlic extract, in conjunction with other nutritional factors, may help to alleviate fatigue and various complaints from athletes and those with colds and various internal diseases (61-68). Aged garlic extract provides nutrients and a protein fraction, which may be conducive to the growth of the beneficial bacteria (69). These bacteria (*B. bifidum* and *L. acidophilus*) produce both acid and anti-bacterial factors which studies have suggested may decrease the growth of pathogens and their production of toxic and carcinogenic compounds (70-72).

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## **MAY AFFORD ANTI-OXIDANT AND RADIO-PROTECTIVE PROPERTIES**

It has been suggested that aged garlic extract may possess an anti-rancidity ability to protect cell membranes (73-76) and an overall ability to quench free radicals (74-76). One study has suggested that aged garlic extract may protect lymphocytes from irradiation damage, whereas fresh garlic worsened conditions more so than in an irradiated control (54). Other studies have suggested that aged garlic extract may protect liver microsomal membranes from chemical and physical damage induced by lipid peroxidation (73) and may protect vascular endothelial cells from oxidant injury upon exposure to hydrogen peroxide, a potent oxidant (76). The endothelial cells lining the vascular system are especially sensitive to attack by free radicals and such attack may contribute to the development and/or progression of cardiovascular diseases. The antioxidant activity of aged garlic extract may also be responsible for its cardioprotective effect against the anti-carcinogenic drug, doxorubicin/andriamycin which has been shown to induce strong oxidative damage to the heart muscle (49,50). Appropriate antioxidant intervention, by inhibiting or reducing free radical toxicity, may offer protection against radiation, and alleviate or delay symptoms of aging and chronic disease (89,90).

---

## **MAY ENHANCE MEMORY AND AFFORD ANTI-AGING PROPERTIES**

Aged garlic extract may ameliorate learning behaviors and memory ability. It has been suggested that immunodeficiency, such as decreased antibody, lymphocyte and splenocyte production, and the decrease in antioxidative enzyme systems are the most important causes of aging (79-81). Aged garlic extract was found to delay the manifestation of learning and memory impairments in senescence accelerated mice which are often used as senile dementia models. Because aged garlic extract has demonstrated antioxidant protective effects in cell membranes (73,76) and an ability to enhance antioxidative and detoxification enzyme activity (15,25,39,43), as well as immunomodulatory effects (38,51-56), it was suggested that aged garlic extract restrained the aging speed via such mechanisms. Further, one study found that aged garlic extract also prolonged the survival and enhanced the branching of cultured neurons (derived from rat embryonic hippocampus), suggesting a neurotrophic effect (81).

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## RECENT DISCOVERIES ON AGED GARLIC EXTRACT

Aged garlic extract has been presented at an array of scientific meetings. Most recently, aged garlic extract was presented at the 2nd International Congress on Phytomedicine in September, 1996 in Munich and the ninetieth annual meeting for the American Urological Association showing anti-cancer effects (30). In May of 1994, over 18 studies were presented at the Designer Foods III Symposium: Research Update on Phytochemicals in Garlic, Soy and Licorice. Studies presented suggested that aged garlic extract could decrease the formation of nitrosamines, demonstrate potent antioxidant activity, improve memory and prevent neuronal degeneration, modulate serotonin receptor levels and down regulate breast cancer promoting prostaglandin E, as well as many other effects. Aged garlic extract was presented at the Adjuvant Nutrition in Cancer Treatment Symposium in April of 1994. In 1990, aged garlic extract was presented in 14 studies at the First World Congress on the Health Significance of Garlic and Garlic Constituents cosponsored by Pennsylvania State University and the United States Department of Agriculture. From 1989 through the present, aged garlic extract was presented at the Annual Meeting of the American Association for Cancer Research. In 1988, 1994, and 1995, aged garlic extract was presented at the annual meeting for the American College of Nutrition. From 1989 through the present, aged garlic extract has been presented at the annual meeting for the Federation of the American Society for Experimental Biology.

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## SAFETY OF AGED GARLIC EXTRACT

The safety of aged garlic extract has been well established by several preclinical and clinical toxicity tests. Raw garlic has been shown to cause edema, bleeding ulcers, depression in weight gain, reduction in red blood cell count and hematocrit (82). Aging, on the other hand, greatly decreases the toxicity of raw garlic and aged garlic extract is almost without toxicity even when a very large dose is taken (82). Acute and subacute toxicity tests (83,84), chronic toxicity tests (85), mutagenicity tests (86) and general toxicity tests have all confirmed the safety of aged garlic extract (87,88). Clinical studies conducted on more than 1,000 subjects also reported no serious side effects from its long term consumption (3,5,61,62,64).

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These statements have not been evaluated by the Food and Drug Administration. This information on Aged Garlic Extract is not intended to diagnose, treat, cure or prevent any disease.

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## Garlique®

### Cardiovascular support

A healthy heart, a healthy life. Garlic has been used for centuries to support a healthy cardiovascular system. Garlic contains the chemicals alliin and allinase. These two chemicals combine to produce allicin — the active ingredient in garlic which most scientists believe is responsible for providing this important support for cardiovascular health.\*

### World leader in product potency

Allicin yield — the amount of allicin that can be produced when the alliin and allinase in garlic combine — is an important measure of garlic's potency and effectiveness. Specially grown in rich fertile soils, the garlic used in GARLIQUE has the very highest allicin yield. It is processed with extreme care and attention, guaranteeing that the potency is preserved as it is ground into a fine ivory white powder. Independent laboratory testing proves that each GARLIQUE tablet yields at least 5000 mcg of allicin.

### Odor-free

GARLIQUE tablets are enteric coated (absorbed in the small intestine, not in the stomach) odor-free, tasteless, easy to swallow and easy to digest. GARLIQUE has none of the unsocial qualities associated with fresh garlic cloves.

### One per day

GARLIQUE tablets are so convenient — you take only one tablet per day to support cardiovascular health.\*

**\* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.**

**Suggested Use:** As an herbal supplement, take one tablet daily, preferably with a meal.

## Supplement Facts

Serving size: 1 tablet

	Amount per Tablet	% Daily Value
Calcium	26 mg	2%
Iron	3 mg	15%
Garlic powder (bulb) (not less than 5000 mcg allicin yield)	400 mg	**

\*\* Daily value not established

**Contains No:** Sugar, starch, yeast, dairy, caffeine or preservatives.

**Caution:** If you are receiving medical treatment for a cardiovascular problem consult your physician. As with any adult supplement, keep this product out of the reach of children.



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 Traditional Homeopathic Medicines

This box contains a Certificate of Analysis

# Nutritionally supports healthy cholesterol levels\*



Recommended by Michael T. Murray, N.D. Dr. Murray is a respected author and a leading researcher in the field of natural health. He is also a practicing naturopathic physician in Bellevue, Washington, and teaches botanical medicine at Bastyr University in Seattle, Washington.

# Garlinase 4000®

The true one-per-day garlic

### One tablet equals:

- 4,000 mg of fresh garlic based on the German Commission E monograph
- Minimum of 5,000 mcg of allicin
- Minimum of 11,000 mcg of alliin
- Rich in gamma-glutamylcysteines and S-allylcysteine

Verified by HPLC analysis



EnzymaticTherapy®  
NATURAL MEDICINES™

Dietary Supplement

No. 08503 • 30 ENTERIC-COATED TABLETS

THIS PRODUCT HAS A TAMPER-EVIDENT FOIL POUCH. DO NOT USE IF FOIL OR PLASTIC IS PUNCTURED!



## Supplement Facts

Serving Size 1 tablet

### Amount per tablet

Garlic (Allium sativum) Bulb Extract (Equal to 4,000 mg of fresh garlic) Standardized to contain a minimum of 3.4% (11,000 mcg) of alliin per tablet	320 mg**
---	----------

\*\*Daily Value not established.

Other ingredients: proprietary enteric coating, cellulose, calcium stearate, cellulose gum and silicon dioxide.

**RECOMMENDATIONS:** One tablet daily with food. **DO NOT CHEW.**

### Compare the advantages of Garlinase 4000®:

- Nutritionally supports healthy cholesterol levels\*
- Each tablet produces a minimum of 5,000 mcg of allicin (highest potency worldwide)
- Patented Swiss process makes it the closest you can get to fresh garlic
- Rich in gamma-glutamylcysteines
- Swiss process increases the availability of the beneficial compounds ajoene and diallyl disulfide
- Certified organically grown
- Verified by High Performance Liquid Chromatography (HPLC). This box contains a Certificate of Analysis from an independent laboratory documenting the exact amount of key compounds in these specific tablets

### The only true one-per-day garlic

Garlinase 4000 fulfills the German Commission E (the world model for regulating herbal products) monograph with just one tablet daily. This monograph recommends a daily intake equal to 4,000 mg of fresh garlic as found in Garlinase 4000.

Other products may claim to be a one-per-day; however, by fulfilling the German Commission E monograph with just one tablet, Garlinase 4000 is clearly the only true one-per-day garlic supplement available in the USA.

### Alliin and the Patented Swiss Process (Patent #5,176,193)

The compounds alliin and alliinase are present in separate chambers of the garlic clove. When garlic is ruptured, alliinase interacts with alliin and converts it to allicin—garlic's most beneficial compound. However, allicin dissipates quickly during standard processing techniques.

The patented Swiss process actually prevents alliinase from interacting with alliin until the enteric-coated tablet is well inside your small intestine. At that time, Garlinase 4000 produces a minimum of 5,000 mcg of allicin per tablet—making it by far the most beneficial garlic supplement on the market. This special Swiss process also ensures completely odor-free breath!

Contains no sugar, salt, yeast, wheat, gluten, corn, soy, dairy products, artificial coloring, artificial flavoring or preservatives.

\*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

We're confident that no one makes a more reliable natural health product than EnzymaticTherapy.™  
"Feel healthy, feel great — Guaranteed!"

Questions or comments, call 1-800-783-2286 (en español, 1-800-552-6338), 8 a.m.-5 p.m. CST, Mon.-Fri. Or visit our web site: [www.garlinase.com](http://www.garlinase.com)

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# Garlique

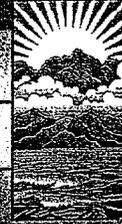
supports cardiovascular health\*

World leader in product potency

Odor-free, all natural, drug-free

30  
tablets  
1 per day

Standardized  
Herbal Supplement



SUNSOURCE

## Garlique supports cardiovascular health\*

### Cardiovascular support

A healthy heart, a healthy life. Garlic has been used for centuries to support a healthy cardiovascular system. Garlic contains the chemicals alliin and alliinase. These two chemicals combine to produce allicin – the active ingredient in garlic which most scientists believe is responsible for providing this important support for cardiovascular health.\*

### World leader in product potency

The potency and effectiveness of garlic is measured in terms of its allicin yield – the amount of allicin that can be produced when the alliin and alliinase combine. GARLIQUE uses only select high allicin yield garlic specially grown in rich, fertile soils. GARLIQUE garlic is processed with extreme care and attention, guaranteeing that the potency is preserved as it is ground into a fine ivory white powder. Independent laboratory testing proves that each GARLIQUE tablet yields at least 5000 mcg of allicin – more than any other leading brand.

### Odor-free

GARLIQUE tablets are enteric coated (absorbed in the small intestine, not in the stomach), odor-free, tasteless, easy to swallow and easy to digest. GARLIQUE has none of the unsocial qualities associated with fresh garlic cloves.

### One per day

GARLIQUE tablets are so high in allicin yield that you have to take only one tablet per day to support cardiovascular health.\*

\* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

**Suggested Use:** As an herbal supplement take one tablet daily, preferably with a meal.

## Supplement Facts

Serving Size: 1 Tablet

### Each Tablet Contains

Garlic powder (bulb) (not less than 5000 mcg of allicin yield)	400 mg**
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\*\* Daily value not established.

**Other Ingredients:** Dicalcium Phosphate, Microcrystalline Cellulose, Croscarmellose Sodium, Stearic Acid, Magnesium Stearate, Sodium Lauryl Sulfate, Colloidal Silicon Dioxide, Hydroxypropyl Methylcellulose Phthalate, Talc, Titanium Dioxide, Triacetin, Pharmaceutical Glaze, (214-112).

**Contains No:** Sugar, starch, yeast, caffeine, dairy or preservatives.

**Caution:** If you are receiving medical treatment for a cardiovascular problem, consult your physician. As with any adult supplement, keep this product out of the reach of children.

Store in a dry place at controlled room temperature. Avoid heat above 86°F (30°C).

**Tamper Evident:** Do not use if blister unit is broken.

**Satisfaction Guaranteed:** If for any reason you are not satisfied with this Sunsource® product, mail us your original store receipt and the remaining unused contents of your package for a full refund. Mail to: Chattem, Inc., Consumer Affairs Dept., 1715 W. 38th Street, Chattanooga, TN 37409.

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**ONE A DAY**  
DIETARY SUPPLEMENT  
USE IN ADDITION TO YOUR MULTIVITAMIN

**Cholesterol Health**

HELPS MAINTAIN HEALTHY CHOLESTEROL LEVELS\*

With Natural Garlic and Soy Extracts

30 TABLETS

FEEL your **BEST**  
Cholesterol Health

With Natural Garlic and Soy Extracts

One-A-Day Cholesterol Health, along with a healthy diet and exercise, helps maintain healthy cholesterol levels\* with key ingredients to help YOU Feel Your Best.

- Natural Garlic
- Natural Soy Extracts
- Vitamin E

Directions: Take two tablets daily, with food.

**Supplement Facts**  
Serving Size: Two tablets  
Servings Per Container: 15

	Amount Per Serving	% Daily Value
Vitamin E	200 IU	667%
Lecithin	100 mg	*
Garlic ( <i>Allium sativum</i> ) (freeze-dried) (bulb)	30 mg	*
Soy Standardized Extract (Glycine max or spp.) (bean)	140 mg	*

\*Daily Value not established

**INGREDIENTS:** Dicalcium Phosphate, Cellulose, dl-alpha-Tocopheryl Acetate, Soy Extract, Gelatin, Lecithin, Croscarmellose Sodium, Hydroxypropyl Methylcellulose, Polyethylene Glycol, Silicon Dioxide, Garlic Powder, Calcium Silicate, Magnesium Stearate, Titanium Dioxide, Hydroxypropyl Cellulose, FD&C Yellow #6 Lake, FD&C Red #40 Lake, FD&C Blue #1 Lake, Polysorbate 80.

**WARNINGS:** Keep out of the reach of children.

\* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

**CHILD RESISTANT CAP**  
Do not use this product if safety seal bearing Sealed For Your Protection under cap is torn or missing.

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At One-A-Day, we've used our years of experience in nutrition to create new products to better address your health concerns. We use only premium-quality, standardized natural extracts that will meet not only our high standards, but yours. Our manufacturing process assures you receive fresh, consistent products every time.

**FORMULATED TO MEET YOUR NEEDS**

One-A-Day Cholesterol Health goes beyond just Garlic. Our formula combines **Natural Garlic** with **Vitamin E**, which supports normal cardiovascular function.\* Plus, we included **Natural Soy Extracts**. Diets that include Soy are associated with healthy cholesterol levels.\*

Use One-A-Day Cholesterol Health alone or in addition to your One-A-Day multivitamin to help you **Feel Your Best.**



NATROL

Once Daily Potency  
**GarliPure™**

Pure, Standardized Garlic  
 with Optimized GarlicActives™



**BUY ONE  
 GET ONE FREE!**

ODOR  
 CONTROLLED  
 30 TABLETS

Dietary  
 Supplement

Helps maintain a healthy cholesterol level. †

NATROL  
 Once Daily Potency  
**GarliPure™**

**Recommendation**

Take 1 tablet daily with a meal. One enteric coated tablet provides 6,000 mcg alliin yield.  
 One Tablet provides 600 mg garlic powder, equivalent to 1/2 fresh garlic clove.

**Other Ingredients:**

Dicalcium Phosphate, Microcrystalline Cellulose, Croscarmellose Sodium, Silicon Dioxide, Stearic Acid, Magnesium Stearate.

†100% Pure-Gar® Garlic Pure-Gar® is a registered trademark of Natrol® Inc.



**Supplement Facts**

Serving Size 1 Tablet	
	Amount Per Serving
Garlic ( <i>Allium sativum</i> ) Powdered Extract (bulb)*	600 mg*
Alliin	13,800 mcg
Thiosulfonates	6,060 mcg
Alliin Yield	6,000 mcg
Gamma Glutamylcysteines	4,800 mcg
Sulphur	3,900 mcg

\*Daily Value not established

Manufactured by NATROL®, Inc. Chatsworth, CA 91311  
[www.natrol.com](http://www.natrol.com) Made in the USA

†This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent disease.

Yields 6,000 Mcg  
 Alliin Per Tablet

Time to change  
 your garlic.™

GarliPure's GarlicActives™ are measured using our laboratory SpectraAll™ testing process to ensure the proper balance of garlic's various marker compounds.

**GarlicActives™ Profile**

Ingredient	Per 600 mg Tablet
Alliin	13,800 mcg
Thiosulfonates	6,060 mcg
Alliin Yield	6,000 mcg
Gamma Glutamylcysteines	4,800 mcg
Sulfur	3,900 mcg

GarliPure garlic is certified and controlled for quality from seed to finished product.

KEEP OUT OF REACH OF CHILDREN.  
 STORE IN A COOL, DRY PLACE.

Yields 6,000 Mcg  
 Alliin Per Tablet

Introducing a garlic supplement unlike any other garlic you have ever taken. Natrol's **GarliPure™** is different because it contains guaranteed standardized yield levels of garlic's key marker compounds including—*alliin, alliin, total sulfur, thiosulfonates, and gamma glutamylcysteines*. We call these active ingredients **GarlicActives™**, and they make **GarliPure™** the new standard for garlic users.

**All Natural Product**

This product is formulated to contain No Yeast, Wheat, Corn, Milk, Egg, Soy, Glutens, Sugar, Artificial Color, Animal Derivatives, Added Starch or Preservatives.