

GR



Original Submission

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68594

# VANCOL INDUSTRIES, INC.

P.O. BOX 11037, DENVER, CO 80211  
1700 EAST 68TH AVE. DENVER, CO 80229  
303-289-8655 FAX ~~303-287-7947~~ 44

December 20, 1999

Office of Premarket Approval (HFS-200)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW.,  
Washington, DC 20204

2000 JAN - 3 A 10: 44

**Notice of GRAS Exemption claim:** Vancol Industries, Inc. has determined that Chromium Picolinate used as an ingredient in a non-carbonated beverage or tea is exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act. Vancol Industries, Inc. has determined that such use is GRAS.

**Notifier name and address:**

Vancol Industries, Inc.  
1700 East 68 th Avenue  
Denver, CO 80229

**Notified substance**

Chromium Picolinate (98.0-100.0% by weight.)

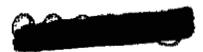
**Condition of use**

Chromium Picolinate is used as an ingredient in a non-carbonated fruit beverage marketed under the brand name ORA. Distribution will achieve the widest consumer availability possible. Distribution channels will include but not be limited to grocery stores, convenience stores, mass merchandisers and drug store chains.

I In ORA Citrus Punch flavor, 10 mcg of Chromium Picolinate is used per 8 oz serving in a bottle that contains 20 fl. oz. or 2.5 servings. It is reasonable to expect that a consumer may drink 1 or more containers per day.

Chromium Picolinate is added to ORA Citrus Punch because Chromium Picolinate enhances the bodies ability to generate energy. Consumers have a tremendous interest in consuming products which can help them achieve higher levels of daily performance in their work and play and which can contribute to their overall health and wellbeing. Chromium Picolinate at the level of 10 mcg per serving safely helps meet those needs.

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**Basis for GRAS determination**

Scientific evidence of safety of the proposed usage of Chromium Picolinate is the basis for GRAS determination.

**Data and information availability**

The data and information that are the basis for this GRAS determination will be sent to the Food and Drug Administration upon request. The data and information that are the basis for this GRAS determination are also available for the Food and Drug Administration's review and copying at reasonable times, upon reasonable notice at the following address:

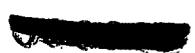
Vancol Industries, Inc.  
1700 East 68<sup>th</sup> Avenue  
Denver, CO 80229

Submitted by: Vancol Industries, Inc.  
1700 E. 68<sup>th</sup>. Ave.  
Denver. CO 80229

~~Robert E. Yates Jr.~~  
~~President~~

Date of submission: December 8, 1999

000012



**Identity of notified substance**

Chromium Picolinate (98-100% by weight.)

**Self-limiting levels of use**

It is unlikely that a consumer would or could consume enough ORA beverage to create an overdose of Chromium Picolinate. The two factors which negate potential for consumption at toxic levels are the fact that the MSDS indicates that the dosage required to create an adverse condition is quite large. The second factor is the low level of Chromium Picolinate in each serving of product. Each 20 oz. bottle of ORA Citrus Punch contains 25 mcg of Chromium Picolinate. The RDI for chromium is 120 mcg per day. A consumer would need to consume 4.8 bottles to ingest a 120 mcg daily dosage of Chromium Picolinate. Since the RDI tends to be a minimum level of consumption required to maintain adequate health, the probable maximum level of ORA consumption (1 to 2 bottles daily) would not create potential for toxicity.

**Basis for GRAS determination of Chromium Picolinate**

Material Safety Data sheet as provided by Ashland Chemical Co., shows the following information:

**HAZARDS IDENTIFICATION****Swallowing**

Swallowing small amounts of this material during normal handling is not likely to cause harmful effects. Swallowing large amounts may be harmful.

**Target Organ Effects**

Overexposure to this material (or its components) has been suggested as a cause of the following effects in humans: anemia.

**Developmental Information**

There are no data available<sup>31</sup> for assessing risk to the fetus from maternal exposure to this material.

**Cancer Information**

There is no information available. The chance of this material causing cancer is unknown. This material is not listed as a carcinogen by the International Agency for Research on Cancer, the National Toxicology Program, or the Occupational Safety and Health Administration.

**Exposure Guidelines**

No exposure limits established.

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**Conclusion**

Chromium Picolinate is safe and is GRAS at the levels and in the application described in this claim.



Source of information:

Ashland Chemical Co.

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December 20, 1999

Office of Premarket Approval (HFS-200)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW.,  
Washington, DC 20204

2000 JAN -3 A 10:48

**Notice of GRAS Exemption claim:** Vancol Industries, Inc. has determined that Ginkgo Biloba Leaf Extract used as an ingredient in a non-carbonated beverage or tea is exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act. Vancol Industries, Inc. has determined that such use is GRAS.

**Notifier name and address:**

Vancol Industries, Inc.  
1700 East 68 th Avenue  
Denver, CO 80229

**Notified substance**

Ginkgo Biloba Leaf Extract of the dried leaf of *Ginkgo biloba* L.

**Condition of use**

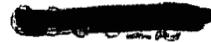
Ginkgo Biloba extract is used as an ingredient in a non-carbonated fruit beverage or tea marketed under the brand name ORA. Distribution will achieve the widest consumer availability possible. Distribution channels will include but not be limited to grocery stores, convenience stores, mass merchandisers and drug store chains.

The Ginkgo Biloba extract is an alcohol and water extract produced from the leaf of Ginkgo Biloba. 1 gram of Ginkgo Biloba leaf yields 4.0 grams of Ginkgo Biloba extract.

30 milligrams of Ginkgo Biloba extract is used per 8 oz serving in a container that contains 20 fl. oz. or 2.5 servings. It is reasonable to expect that a consumer may drink 1 or more containers per day.

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Ginkgo Biloba extract is added to ORA beverages because it is widely known that Ginkgo Biloba enhances memory and improves cardio vascular function. Consumers have a tremendous interest in consuming products which can help them achieve higher levels of daily performance in their work and play and which can contribute to their overall health and wellbeing. Ginkgo Biloba safely meets those needs.



**Basis for GRAS determination**

Scientific evidence of safety of the proposed usage is the basis for GRAS determination.

**Data and information availability**

The data and information that are the basis for this GRAS determination will be sent to the Food and Drug Administration upon request. The data and information that are the basis for this GRAS determination are also available for the Food and Drug Administration's review and copying at reasonable times, upon reasonable notice at the following address:

Vancol Industries, Inc.  
1700 East 68<sup>th</sup> Avenue  
Denver, CO 80229

Submitted by: Vancol Industries, Inc.  
1700 E. 68<sup>th</sup> Ave.  
Denver, CO 80229

~~Robert E. Yates Jr.~~  
President

Date of submission: December 8, 1999

000016



### **Identity of notified substance**

Ginkgo Biloba Leaf Extract of the dried leaf of *Ginkgo biloba* L. The extract is an alcohol and water extract produced from the leaf of Ginkgo Biloba. 1 gram of Ginkgo leaf yields 4.0 grams of Ginkgo Biloba extract.

### **Self-limiting levels of use**

It is unlikely that a consumer would or could consume enough ORA beverage to create an overdose of Ginkgo Biloba. The two factors which negate potential for overconsumption are the fact that there is no known level at which one can overdose on Ginkgo Biloba. The second factor is the low level of Ginkgo Biloba in each serving of product. Each 20 oz. bottle of ORA contains the equivalent of 18.75 mg. of Ginkgo Biloba leaf equal to 0.375 mg of 50:1 extract used as the standard by Commission E. A consumer would need to consume 320 bottles to ingest a 120 mg daily dosage of 50:1 extract used as the standard by Commission E. Even if the consumer were taking a typical Ginkgo Biloba supplement of 200 mg. per day, a reasonable level of ORA consumption (1 to 2 bottles) would not create potential for toxicity.

### **Basis for GRAS determination of Ginkgo Biloba**

Professor Varro E. Tyler, Ph.D., Sc.D., Dean and Distinguished Professor of Pharmacognosy Emeritus, School of Pharmacy and Pharmacal Sciences, Purdue University has called the German Commission E Monographs "the most accurate information available in the entire world on the safety and efficacy of herbs and phytomedicines."

In 1978, the German *Bundesgesundheitsamt* (Federal Health Agency), now called the Federal Institute for Drugs and Medical Devices, established an expert committee on herbal remedies, composed principally of members proposed by associations of the health professions, to evaluate the safety and efficacy of phytomedicines. This so-called "Commission E" included physicians, pharmacists, pharmacologists, toxicologists, representatives of the pharmaceutical industry, and lay persons.

In its assessments, Commission E actively checks so-called bibliographic data independently. Such data include information obtained from clinical trials, field studies, collections of single cases, scientific literature, including facts published in the standard reference works and expertise of medical associations. If controlled clinical data are lacking, safety and efficacy can still be determined on the basis of information in the literature, the presence of supplemental data supporting clinical results, and significant experimental studies supporting traditional use.

Application of this kind of evaluation process results in the establishment of "reasonable certainty" of the safety and efficacy of the herb being evaluated.

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The Monograph for Ginkgo Biloba Leaf Extract, published July 19, 1994, shows:

**Composition:**

A dry extract (35-67:1) from Ginkgo Biloba L. leaf  
(Fam. Ginkgoaceae), extracted with acetone/water.  
Drug/extract ratio on average 50:1.

**Dosage:**

Daily dosage: 120-240 mg native dry extract.

**Side Effects:**

Very seldom stomach or intestinal upsets, headaches or allergic  
skin reaction.

**Interactions with Other Drugs**

None known

**Contraindications:**

Hypersensitivity to Ginkgo Biloba preparations.

**Special Cautions in Use:**

None known.

**Use During Pregnancy and Lactation**

No restrictions known

**Overdosage:**

None known

**Special Warnings**

None.

**Effects on Operators of Vehicles and Machinery:**

None known

**Conclusion**

Ginkgo Biloba is safe and is GRAS at the levels and in the application described  
in this claim.

**Source of information:**

The Complete German Commission E Monographs  
Therapeutic Guide to Herbal Medicines  
Published by: American Botanical Council  
Austin, Texas  
1998

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P.O. BOX 11037, DENVER, CO 80211  
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2000 JAN -3 A 10:44

December 20, 1999

Office of Premarket Approval (HFS-200)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW.,  
Washington, DC 20204

**Notice of GRAS Exemption claim:** Vancol Industries, Inc. has determined that Ginseng extract of the dried main and lateral root and root hairs of Panax Ginseng used as an ingredient in a non-carbonated beverage or tea is exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act. Vancol Industries, Inc. has determined that such use is GRAS.

**Notifier name and address:**

Vancol Industries, Inc.  
1700 East 68 th Avenue  
Denver, CO 80229

**Notified substance**

Ginseng Extract of the dried main and lateral root and root hairs of Panax Ginseng  
C.A. Meyer (Fam. Araliaceae).

**Condition of use**

Ginseng extract is used as an ingredient in a non-carbonated fruit beverage or tea marketed under the brand name ORA. Distribution will achieve the widest consumer availability possible. Distribution channels will include but not be limited to grocery stores, convenience stores, mass merchandisers and drug store chains.

The Ginseng extract is an alcohol and water extract produced from the root of Panax Ginseng 1 gram of Ginseng root yields 5.57 grams of Ginseng extract. The source of the root is the US.

150 milligrams of Ginseng extract is used per 8 oz serving in a container that contains 20 fl. oz. or 2.5 servings. It is reasonable to expect that a consumer may drink 1 or more containers per day.

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Ginseng extract is added to ORA beverages because it is widely recognized as a "tonic for invigoration and fortification in times of fatigue and debility, for declining capacity for work and concentration" to quote the German Commission E Monograph.

Consumers have a tremendous interest in consuming products which can help them achieve higher levels of daily performance in their work and play and which can contribute to their overall health and wellbeing. Ginseng safely meets those needs.

**Basis for GRAS determination**

Scientific evidence of safety of the proposed usage of Ginseng is the basis for GRAS determination.

**Data and information availability**

The data and information that are the basis for this GRAS determination will be sent to the Food and Drug Administration upon request. The data and information that are the basis for this GRAS determination are also available for the Food and Drug Administration's review and copying at reasonable times, upon reasonable notice at the following address:

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Submitted by: ~~Vancol~~ Industries, Inc.  
~~1700 E. 68<sup>th</sup> Ave.~~  
~~Denver, CO 80229~~

~~Robert E. Yates Jr.~~  
~~President~~

Date of submission: ~~December 8, 1999~~

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### **Identity of notified substance**

Ginseng extract of the dried main and lateral root and root hairs of *Panax Ginseng* C.A. Meyer (Fam. Araliaceae). The extract is an alcohol and water extract produced from the root of *Panax Ginseng*. 1 gram of Ginseng root yields 5.57 grams of Ginseng extract. The source of the root is the US.

### **Self-limiting levels of use**

It is unlikely that a consumer would or could consume enough ORA beverage to create an overdose of Ginseng. Each 20 oz. bottle of ORA contains the equivalent of 67.32 mg. of Ginseng root. A consumer would need to drink nearly 15 bottles to ingest 1 gram equivalent of Ginseng root. Even if the consumer were taking a typical Ginseng supplement of 500 mg. per day, a reasonable level of ORA consumption (1 to 2 bottles) would not create potential for toxicity.

### **Basis for GRAS determination of Ginseng**

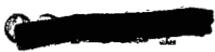
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In 1978, the German *Bundesgesundheitsamt* (Federal Health Agency), now called the Federal Institute for Drugs and Medical Devices, established an expert committee on herbal remedies, composed principally of members proposed by associations of the health professions, to evaluate the safety and efficacy of phytomedicines. This so-called "Commission E" included physicians, pharmacists, pharmacologists, toxicologists, representatives of the pharmaceutical industry, and lay persons.

In its assessments, Commission E actively checks so-called bibliographic data independently. Such data include information obtained from clinical trials, field studies, collections of single cases, scientific literature, including facts published in the standard reference works and expertise of medical associations. If controlled clinical data are lacking, safety and efficacy can still be determined on the basis of information in the literature, the presence of supplemental data supporting clinical results, and significant experimental studies supporting traditional use.

Application of this kind of evaluation process results in the establishment of "reasonable certainty" of the safety and efficacy of the herb being evaluated.

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The Monograph for Ginseng root, published January 17, 1991, shows:

**Composition:**

Ginseng root consists of the dried main and lateral root and root

**Dosage:**

Unless otherwise prescribed:

Daily dosage: 1-2 grams of root or equivalent preparations.

**Side Effects:**

None known.

**Interactions with Other Drugs**

None known

**Contraindications:**

None known.

**Conclusion**

Ginseng is safe and is GRAS at the levels and in the application described in this claim.

**Source of information:**

The Complete German Commission E Monographs  
Therapeutic Guide to Herbal Medicines  
Published by: American Botanical Council  
Austin, Texas  
1998

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**SUBMISSION END**

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# VANCOL INDUSTRIES, INC.



1700 E. 68th AVENUE • DENVER, CO 802  
P.O. BOX 11037 • DENVER, CO 802  
303-289-8655 • FAX 303-287-79

DATE: 4/10/00

TIME: \_\_\_\_\_

TRANSMITTAL TO: MR LAWRENCE LIN

COMPANY/FIRM: FDA

FAX NUMBER: 202 418 3131

FAX FROM: John Rawick

NUMBER OF PAGES (including cover sheet): 2

OPERATORS NAME: \_\_\_\_\_

COMMENTS: \_\_\_\_\_  
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**IF TRANSMITTAL IS NOT COMPLETE, PLEASE CALL 303-289-8655.**

# VANCOL INDUSTRIES, INC.

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P.O. BOX 11037, DENVER, CO 80211  
1700 EAST 68TH AVE. DENVER, CO 80229  
303-289-8655 FAX 303-287-7947

April 10, 2000

Mr. Lawrence J. Lin Ph.D.  
Division of Petition Control, HFS-215  
Office of Premarket Approval  
Food and Drug Administration  
Washington, DC 20204

Subject: GRAS Notice (GRN) No. 000036

Dear Mr. Lin,

This memo is to inform the FDA that Vancol Industries, Inc. is withdrawing its Notice of GRAS Exemption Claims for chromium picolinate, Ginkgo biloba and Panax ginseng. Please remove the notice from the FDA web site.

Thank you for your assistance.

Best regards. 

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John Ravnik  
Special Projects Manager

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# VANCOL INDUSTRIES, INC.

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April 10, 2000

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Best regards. 

John Ravnik  
Special Projects Manager

000030