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ORIGINAL SUBMISSION

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September 5, 2000

Office of Premarket Approval (HSF-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, Washington DC 20204

2000 SEP -8 P 3:43

Dear Sirs,

In accordance with the Federal Register 62 FR 18937, dtd April 17, 1997, Permafresh Corporation is submitting a GRAS Notice for Argon gas used as a food substance.

Enclosed are three copies of our claim for your review.

Thank you for your consideration.

Sincerely,

Tim Thorsen
COO, Permafresh Corporation
8911 Osuna Road NE
Albuquerque, NM 87111
(505) 577-2235
thorsen@permafresh.com

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September 1, 2000

Office of Premarket Approval (HSF-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, Washington DC 20204

Generally Recognized as Safe (GRAS) Notification

Permafresh Corporation Claim: Argon gas, as a food substance, is exempt from the statutory premarket approval requirements of the Federal Food, Drug and Cosmetic Act. This claim is based on our determination that within the scope of uses described below, argon gas is Generally Recognized as Safe (GRAS).

Submitted by:
George W. Liebmann, Jr.
Permafresh Corporation CEO
153 Michelle Drive
Santa Fe, NM 87501

Notified substance: Argon

Conditions of use:

All argon gas used by Permafresh™ as a food substance is of High Purity (quality). It is 99.998 % pure argon, with the 0.002% impurities primarily consisting of nitrogen. Through patented processes argon gas will replace a "normal air" atmosphere in sealed containers. The foods in which argon gas will be used include premium wines and all-natural, unpasteurized fruit and vegetable juices. An "application", used to vacate ambient air, will not exceed 0.71 ounces of pure argon gas. The purpose of establishing an argon atmosphere is to significantly delay the bacterial/chemical processes primarily responsible for food spoilage. The physical functional effect of an argon additive is food preservation; it acts as both an antioxidant and antimicrobial agent by removing the "food" that fuels spoiling. A very low portion of the world's population would be exposed to argon gas preservation. The user population would be a small fraction of mid to upper income premium wine drinkers and people who consume commercial all-natural, freshly squeezed fruit and vegetable juices.

Basis for GRAS determination: Scientific procedures

All data and information that form the basis for the Permafresh GRAS determination are available for the Food and Drug Administration's review and copying and may be viewed at the above address or can be forwarded to FDA on request.

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Description of Argon gas: Argon is a monatomic, chemically inert gas composing 0.93% of normal air. Its symbol is Ar, atomic number is 18 and atomic weight is 39.948. Argon is normally found in its gaseous state with a specific gravity of 1.38 and a boiling point of 302.6 °F. Argon is colorless, odorless, tasteless, noncorrosive, nonflammable and nontoxic. Argon gas, although not life sustaining as the only element in an atmosphere, has no known direct or side effect on humans through contact and its flows harmlessly back into the atmosphere when released. It contains no potential human toxicants. Argon is very stable, twice as dense as air and not known to form true chemical compounds. The human body naturally contains about 6 ppb (parts per billion) of Argon by weight. The name Argon comes from the Greek word "Argos" meaning "inactive".

Common Name: Argon gas

Chemical Name: Argon

CAS Registry Number: 7440-37-1

Empirical and Structural Formula: ${}_{18}\text{Ar}^{40}$

Specifications for food grade material: High Purity, 99.998% pure Ar

Quantitative Compositions: Argon, being a noble gas, does not readily combine with other atoms to form new /modified materials. There are no known Binary Compounds formed in the presence of Argon.

Manufacturing Process: Argon is a product of cryogenic air separation, where liquefaction, distillation and purification processes are used to commercially produce High Purity Argon gas.

Although Permafresh™ intends to limit a "standard" argon application to less than one ounce for the above conditions of use, there is no scientific evidence indicating that an upward limit/self limit must be imposed.

Argon, as a food substance, is GRAS. Discussion:

Although I can find no documented history of pure Ar used regularly with foods, air, and thus Ar, has come in contact with food ever since an earth atmosphere was formed. According to experts in gas manufacturing and the food packaging industries, Argon, primarily in combination with N₂ and CO₂, has been used to preserve freshness in food packaging and transportation to processing/market for over 30 years (statement available on request). An existing wine preservation product called "Private Preserve" (<http://www.privatepreserve.com/>) claims to use Argon as a primary preservation agent, but the gas applied is air with the O₂ removed. Permafresh™ first used Ar during our product research and development stages as early as 1994.

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Many scientific publications, including some of those referenced below, refer to the similar property characteristics Ar shares with Helium (He) and, to a lesser extent, Nitrogen (N₂). As Argon, both He and N₂ are naturally occurring elements and suitable characteristic counterparts. He and N₂ are currently listed as "Direct Food Substances Affirmed as Generally Recognized As Safe" (He: 21CFR184.1355 and N₂: 21CFR184.1540).

Argon is totally inert. Food preserved with Argon will not chemically combine or readily mix with this gas. The sole purpose of an Ar blanket is to significantly deter/slow the spoiling process in foods. Consumption of Argon through the ingestion of food preserved with Argon is not likely. If ingestion occurred, however, no scientific evidence can be found claiming a detrimental human. Food may easily be tested for the presence of Argon using a common gas spectrometry analysis of the food. A focused gas spectrometry analysis is sufficiently sensitive and reproducible to detect the smallest amounts of Argon present.

There are thousands of published articles in scientific literature attesting to the totally inert, nontoxic, environmentally friendly qualities of Argon. Several are listed below:

- (1) J.E Huheey, E. A. Keiter and R.L. Keiter in *Inorganic Chemistry: Principles of Structure and Reactivity*, 4th edition, HarperCollins, New York, USA 1993.
- (2) N. N. Greenwood and A. Earnshaw in *Chemistry of the Elements*, 2nd edition, Butterworth, UK, 1997.
- (3) F. A. Cotton, G. Wilkinson, C. A. Murillo and M. Bochmann in *Advanced Inorganic Chemistry*, John Wiley & Sons, 1999.
- (4) D.R. Lide, (ed.) in *Chemical Rubber Company Handbook of Chemistry and Physics*, CRC Press, Boca Raton, Florida, USA, 77th edition, 1996.
- (5) Theodore L. Brown and H. U. Gene LeMay in *Chemistry, the Central Science*, 3rd edition, Prentice Hall, 1985
- (6) Argon Data Sheet:
http://www.c-f-c.com/specgas_products/argon.htm
- (7) Cary Academy Argon Fact Sheet:
<http://web1.caryacademy.pvt.k12.nc.us/chemistry/rushin/StudentProjects/ElementWebsites/argon/>
- (8) Argon Material Safety Data Sheet:
<http://www.hoopersupply.com/msds/argon.htm>
- (9) Argon Biological Information:
<http://www.webelements.com/webelements/elements/text/Ar/biol.html>

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Permafresh has three opinion letters from experts in scientific fields attesting to the GRAS and non-invasive qualities of Argon as a food substance. These scientists were obtained through the University of New Mexico School of Chemistry and Los Alamos National Laboratories and have no personal interest in Permafresh™.

- (1) Dr. David Whitten, co-founder and Chief Technical Officer of QTL Biosystems, LLC in Santa Fe, NM (Biochemistry).
- (2) Dr. Joel Swadesh, CEO of Seraf Therapeutics, Albuquerque, NM (Physical Chemistry).
- (3) Mr. Kevin Lozeau, Senior Engineer at Smart Design, LLC, New York, NY (Engineering).

Permafresh™ research and scientific experts have been unable to uncover any reports of investigations or other information that may appear as inconsistent with a GRAS determination for Argon.

In conclusion, we have found that there is consensus among interviewed and published experts, qualified by scientific training and experience to evaluate the safety of Argon added to food, that there is reasonable certainty that High Purity Argon is not harmful under the intended conditions of use.

Claim Notifier:

George W. Liebmann, Jr.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

September 20, 2000

Mr. George W. Liebmann, Jr.
Permafresh Corporation
153 Michelle Drive
Santa Fe, NM 87501

Re: GRAS Notice (GRN) No. 000057

Dear Mr. Liebmann:

The Food and Drug Administration (FDA) has received the notice, dated September 5, 2000, that you submitted on behalf of Permafresh Corporation in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS)). FDA received this notice on September 12, 2000 and designated it as GRN No. 000057.

The subject of the notice is argon gas. The notice informs FDA of the view of Permafresh Corporation that argon gas is GRAS, through scientific procedures, to replace the normal air atmosphere in sealed containers for wines, fruit and vegetables at a level not to exceed 0.71 ounces of pure argon gas.

In accordance with proposed 21 CFR 170.36(f), a copy of the information in your notice that conforms to the information described in proposed 21 CFR 170.36(c)(1) is available for public review and copying on the Office of Premarket Approval's homepage on the Internet. If you have any questions about the notice, contact Dr. Linda Kahl at 202-418-3101.

Sincerely yours,

Suzette Williams
Division of Product Policy, HFS-205
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

Hard copy cc: GRN 000057 (1 copy)
Electronic mail cc: HFS-206(LKahl)
Electronic reading file P:\opa\common\correspond\... \gn000057ak.let
Filename: gn000057ak

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FILE
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OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
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SUBMISSION END

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