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Via Hand Delivery

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Office of Food Additive Safety (HFS-255)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
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Writer's Direct Access
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Re: GRAS Notification for Sodium Nitrite (NaNO₂) Intended for Addition to the Surface of Fresh Beef Via Migration From Food Packaging Film

Dear Dr. Martin:

Pursuant to proposed 21 C.F.R. § 170.36 and on behalf of Bemis Company, Inc., we are submitting the enclosed notification to the Food and Drug Administration indicating that sodium nitrite is exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act because it has been determined, on the basis of scientific procedures, to be generally recognized as safe (GRAS) when added in small amounts to the surface of fresh ground beef and fresh whole muscle cuts of beef via migration from sodium nitrite-containing food packaging film.

Enclosed please find three copies and one electronic copy on disk of the notification and accompanying documents. In addition, a fourth copy is provided for the USDA's Food Safety and Inspection Service (FSIS) since the intended use of the substance involves direct addition to meat products. We also have separately delivered a courtesy copy to Mr. Charles Gioglio at FSIS's Labeling and Consumer Protection Staff office.

If you have any questions regarding this notification, please contact either of us at the above numbers or email addresses.

Cordially yours,

Melvin S. Drozen

Elizabeth N. Harrison

cc: Mr. Charles L. Gioglio, USDA

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Before the
FOOD AND DRUG ADMINISTRATION
Department of Health and Human Services
Washington, D.C.

GRAS NOTIFICATION

Name of Notifier: Bemis Company, Inc.

Name of Substance: Sodium Nitrite (NaNO_2) intended for addition to the surface of raw ground beef and raw whole muscle cuts of beef via migration from Bemis Company's packaging film

Intended Use: To maintain the characteristic color of raw beef when vacuum packaged in a high-oxygen-barrier film

Dated: June 27, 2007

Submitted by: Melvin S. Drozen
Elizabeth N. Harrison
Keller and Heckman LLP
Counsel for Notifier

Table of Contents

Introduction.....	3
I. Administrative Information.....	4
A. Name and Address of the Notifier.....	4
B. Name of the Substance.....	4
C. Intended Conditions of Use.....	4
D. Basis for GRAS Determination.....	5
E. Statement of Availability of Data.....	5
II. Identity of the Notified Substance.....	6
A. General Description.....	6
B. Specifications.....	6
C. Description of the Sodium Nitrite-Containing Film.....	6
III. Detailed Summary of the Basis for Notifier's Determination of GRAS Status.....	7
A. Amount of Sodium Nitrite Added to Meat.....	7
B. Added Sodium Nitrite Undergoes Reactions and Is Converted to Other Substances.....	8
1. Sodium Nitrite.....	9
2. Nitric oxide.....	9
3. Nitrosomyoglobin.....	10
4. Nitrate.....	10
C. Safety of Added Nitrite.....	12
1. Existing Regulations Permit Added Nitrite in Food.....	12
2. Scientific Studies on Nitrite Safety.....	13
a. Absorption, Distribution and Elimination.....	13
b. Acute Toxicity.....	13
c. Reproductive Toxicity.....	14
d. Mutagenicity.....	14
3. Reviews of Nitrite by Scientific Organizations.....	15
4. Exposure to Nitrite from Nitrate Metabolism and Nitrate-Containing Foods.....	18
a. Endogenous Production of Nitrite from Dietary Nitrate.....	18
b. Exposure to Nitrite from Dietary Nitrite.....	18
c. Exposure to Nitrite from Bemis's Packaging Film.....	19
5. The Amount of Dietary Nitrite from Bemis's Packaging Film is Trivial, Safe, and GRAS.....	19
6. Safety Studies on Nitrate.....	20
IV. Reports of Investigations Inconsistent with GRAS Status.....	20
V. Functionality.....	21
A. The Added Sodium Nitrite is Effective at Maintaining The Color of Raw Beef While In the Vacuum Package.....	21
B. Once Removed from the Package, Beef Packaged in Sodium Nitrite-Containing Film Fades to a Duller Color than Beef Packaged in Plain Film.....	21
C. The Amount of Sodium Nitrite Added is the Minimum Amount Needed.....	22
VI. Labeling.....	22
VII. Conclusion: Sodium Nitrite Added to Raw Beef Products via Migration from Bemis's Vacuum Packaging Film is GRAS.....	23

GRAS NOTIFICATION

Sodium Nitrite Added to Beef

Via Migration from Packaging Film

Introduction

Bemis Company, Inc. submits the enclosed dossier of information in support of this notification that sodium nitrite (NaNO_2) is generally recognized as safe (GRAS) when added in small amounts to the surface of raw ground beef and raw whole muscle cuts of beef via its migration from packaging film. Bemis manufactures the sodium nitrite-containing packaging film in accordance with current good manufacturing practices (cGMP), and the intended effect of the sodium nitrite is to help maintain the characteristic color of raw beef while it is in the package. The determination of GRAS status is on the basis of scientific procedures in accordance with 21 C.F.R. § 170.30(b), and conforms to the guidance issued by the Food and Drug Administration (FDA) under proposed 21 C.F.R. § 170.36 (62 Fed. Reg. 18938; April 17, 1997).

We submit information in the following areas:

- Identity of the substance.
- Estimated exposure to sodium nitrite and potential associated compounds (nitric oxide, nitrate, and nitrosomyoglobin) under the intended conditions of use.
- Safety data for nitrite and each potential associated substance.
- Safety evaluation of the exposure to nitrite and each associated substance resulting from the proposed use.
- Basis for the Notifier's determination that the proposed use of sodium nitrite is GRAS based on scientific procedures.
- Information showing that sodium nitrite helps to maintain the color of raw ground beef and raw whole muscle cuts of beef while in the vacuum package, and the mechanism by which this is accomplished.

It is our expectation that FDA will concur that the information presented herein and in the attached appendices supports fully the determination that sodium nitrite is GRAS when, for the purpose of maintaining color, it is added in small amounts to the surface of raw ground beef and raw whole muscle cuts of beef via migration from sodium nitrite-containing packaging film produced by Bemis Company

I. Administrative Information

A. Name and Address of the Notifier

Bemis Company, Inc.
One Neenah Center
4th Floor
P.O. Box 669
Neenah, WI 54957

All Communications on this matter are to be sent to Counsel for the Notifier:

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Telephone: (202) 434-4222 (M. Drozen); (202) 434-4111 (E. Harrison)
Facsimile: (202) 434-4646
Email: drozen@khlaw.com; harrison@khlaw.com

B. Name of the Substance

The common or usual name of the substance added to ground beef and whole muscle cuts of beef is sodium nitrite. The sodium nitrite is imbedded in one side of a unique packaging film that Bemis Company has developed. The packaging film is produced in several different thicknesses, each containing a different amount of sodium nitrite, for packaging different cuts of beef (e.g., ground beef, strip steaks, filet mignon, etc.). These different levels of sodium nitrite are necessary to deliver the minimum amount of sodium nitrite necessary to the surface of the different beef cuts.

C. Intended Conditions of Use

Sodium nitrite is added to the surface of raw whole muscle cuts of beef and ground beef via its migration from nitrite-containing packaging film to help maintain the characteristic color of raw beef while it is in the package. The beef is packaged in the film using vacuum packaging technology at a central facility, and then delivered to retail outlets for display to consumers. The packaged meat is "case ready" when it arrives at the retail outlet and there is no product manipulation at the retail outlet.

After the meat is placed within the packaging film and the air in the package is removed (i.e., vacuum packaging), the sodium nitrite in the film migrates from the film to the meat's surface, where it forms nitric oxide, which then reacts with myoglobin in the meat (nitrosylation) to produce nitrosomyoglobin. The added nitrite allows the meat to maintain the characteristic red color of raw beef that consumers desire. The amount of sodium nitrite added to the surface of the meat is significantly below the established Acceptable Daily Intake (ADI) for nitrite.

GRAS NOTIFICATION

Sodium Nitrite Added to Beef

Via Migration from Packaging Film

Raw beef products packaged in Bemis's packaging film retain their attractive red color while in the package. After removal from the packaging, however, the color fades. The packaged beef will be labeled with an ingredient statement declaring the added sodium nitrite and a "Use by" or "Freeze by" date to indicate the date by which the product should be used or frozen. The beef products' labels also will bear appropriate cooking and handling directions indicating that the beef should be cooked to an appropriate temperature and not to use meat color as an indicator of doneness.

D. Basis for GRAS Determination

The addition of sodium nitrite to raw meat is generally recognized as safe based on scientific procedures, in accordance with 21 C.F.R. § 170.30. The basis of Bemis Company's determination of GRAS status is discussed more fully below and supported by data presented in the accompanying documents.

E. Statement of Availability of Data

The data and information that are the basis for this GRAS determination are provided in Appendices to this Notification, or will be provided to FDA upon request.

* * *

The foregoing and attached information considered, we respectfully submit that the addition of sodium nitrite to the surface of raw beef products via exposure to Bemis Company's sodium nitrite-containing packaging film is exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act because such use is GRAS.

Respectfully submitted,

Bemis Company, Inc.

By Melvin S. Drozen, Esq.

Elizabeth N. Harrison, Esq.
Keller and Heckman LLP
COUNSEL FOR THE NOTIFIER

II. Identity of the Notified Substance

A. General Description

The notified substance is sodium nitrite.

Chemical name: Sodium Nitrite

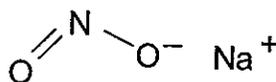
Chemical Abstract Service (CAS) Registry Number: 7632-00-0

INS Number: 250

Empirical formula: NaNO_2

Formula weight: 69.01 Daltons

Structural Formula:



B. Specifications

Specifications for Bemis's food-grade sodium nitrite conform to the specifications listed in the Food Chemicals Codex (5th Edition, 2004). A copy of these specifications, as well as a Material Safety Data Sheet for the sodium nitrite, is provided in Appendix 1. Also provided in Appendix 1 is data regarding the identity of the film's component resins.

C. Description of the Sodium Nitrite-Containing Film

Unlike a typical food ingredient that is added directly to food during manufacturing, the sodium nitrite that is the subject of the present Notification is added to beef via migration from a food packaging material. Specifically, Bemis Company has developed a food packaging film that contains sodium nitrite on one side of the film. All other components of the film comply with the Federal Food, Drug, and Cosmetic Act and FDA's regulations implementing the Act and are permitted for use in food contact applications.

The packaging film is intended to be used to wrap vacuum packaged beef, with the sodium nitrite-containing layer contacting the meat's surface. As a result of this contact, the sodium nitrite dissolves into the meat juices and diffuses onto the meat's surface where it is converted to nitric oxide (NO) gas by substances naturally present in the meat tissue. The nitric oxide gas then reacts with muscle myoglobin to produce nitric oxide myoglobin (also known as nitrosomyoglobin; NOMb), which fixes or maintains the desired red color while the beef is in the package.

Since different cuts of beef contain different levels of myoglobin, which require different amounts of sodium nitrite to effectively maintain the color of raw beef, Bemis Company produces a range of packaging films, each of which contains a different loading level of sodium nitrite. The amount of sodium nitrite present in Bemis's packaging films ranges from 25 to 113 milligrams per square meter of packaging film (mg/m^2). Water extraction studies indicate that the extent of nitrite

GRAS NOTIFICATION

Sodium Nitrite Added to Beef

Via Migration from Packaging Film

migration from the film into the meat ranges from 60% to 100%. To be conservative, our dietary intake calculations utilize nitrite values for packaging film with the maximum sodium nitrite content - 113 mg/m² - and assume 100% migration of the nitrite from the film to the beef.

III. Detailed Summary of the Basis for Notifier's Determination of GRAS Status

A. Amount of Sodium Nitrite Added to Meat

The proposed use of Bemis's sodium nitrite-containing film to vacuum package raw ground beef and raw whole muscle cuts of beef results in the addition of very small amounts of sodium nitrite to the beef. As noted above, the maximum amount of sodium nitrite present in Bemis's packaging films is 113 mg/m². Assuming 100% migration of the sodium nitrite into the packaged meat, using FDA's assumption that 10 g of food contacts 1 square inch of wrapping^{1/}, and using FDA's daily beef consumption value of 300 grams^{2/}, the maximum daily exposure to sodium nitrite from Bemis's packaging film is 2.19 mg. This is equivalent to a maximum daily nitrite ion (NO₂⁻) intake of 1.46 mg. (The calculations are detailed in Table 1.) As discussed below, this expected intake of nitrite -- 1.46 mg /p/day -- is well below the established Acceptable Daily Intake (ADI) for nitrite of 4.2 mg/p/day.

^{1/} See Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration, Guidance for Industry: Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations (April 2002).

^{2/} See Food and Drug Administration/Center for Veterinary Medicine Guideline #3 at §§ IV.A and IV.B ("Calculating the Acceptable Daily Intake," "Consumption Values").

Table 1
Maximum Amount of Sodium Nitrite and Nitrite Ion Added to Raw Beef

Conversion Factors:

$$1 \text{ sq in} = 6.45 \text{ cm}^2 \quad 1 \text{ m}^2 = 10,000 \text{ cm}^2 \quad \text{NaNO}_2 \text{ contains } 66.7\% \text{ NO}_2^- \text{ }^{\text{3/}}$$

FDA's Default Values:

$$10 \text{ g of food contacts } 1 \text{ in}^2 \text{ of packaging} \quad \text{Avg daily intake of beef} = 300 \text{ g}$$

Calculations:

$$\begin{aligned} &\text{Bemis's packaging film contains } 113 \text{ mg sodium nitrite/m}^2 \text{ film or } 0.0113 \text{ mg/cm}^2. \\ &10 \text{ g food/1 in}^2 \text{ film} = 10 \text{ g food/6.45 cm}^2 \text{ film} = 1.55 \text{ g food/cm}^2 \text{ film.} \\ &0.0113 \text{ mg NaNO}_2/\text{cm}^2 \times [1 \text{ cm}^2/1.55 \text{ g meat}] \times 300 \text{ g meat} = 2.19 \text{ mg sodium nitrite} \\ &2.19 \text{ mg sodium nitrite} \times 0.667 = 1.46 \text{ mg nitrite ion per 300 gram portion of beef}^{\text{4/}} \end{aligned}$$

B. Added Sodium Nitrite Undergoes Reactions and Is Converted to Other Substances

After the sodium nitrite migrates from the film into the beef, it is converted via several sequential chemical reactions into various substances.^{5/} One such substance is nitric oxide (NO), and another is nitric oxide myoglobin, also known as nitrosomyoglobin (NOMb). Small amounts of sodium nitrate can also be produced in the beef, having been converted from nitrite to nitrate by the meat juices. Finally, it is appropriate to determine if any un-reacted sodium nitrite remains in the meat. Set forth below are data and information on the expected dietary exposure to these substances.

^{3/} The molecular weight of nitrite ion (NO₂⁻) is 46 (14 + 32), and the molecular weight of sodium nitrite (NaNO₂) is 69 (23 + 14 + 32). $46 \div 69 = 0.667$. $2.19 \text{ mg sodium nitrite/day} \times 0.667 \text{ mg nitrite ion/mg sodium nitrite} = 1.46 \text{ mg nitrite ion/day}$.

^{4/} Importantly, this calculation is conservative because most cuts of beef and portions of ground beef are sold in larger portions than 300 g, which would have a lower percentage of the beef product actually in contact with the packaging film.

^{5/} Several chemical reactions of relevance occur after sodium nitrite is added to raw meat. See Giddings GG (1977). "Symposium: The Basis of Quality in Muscle Foods; The Basis of Color in Muscle Foods." J Food Sci 42(2): 288-294. Under the proposed use conditions, *i.e.*, with raw meat at low temperature, minimal added nitrite and low oxygen, the expected final products in the meat are nitric oxide (NO), nitric oxide myoglobin (NOMb), nitrate and smaller quantities of various myoglobin pigments.

GRAS NOTIFICATION

Sodium Nitrite Added to Beef

Via Migration from Packaging Film

1. Sodium Nitrite

Bemis's vacuum packaging film is designed to efficiently maintain the characteristic color of raw beef by adding the minimum amount necessary of sodium nitrite. Bemis Company has determined that this characteristic color can be maintained by adding only enough sodium nitrite to nitrosylate roughly half of the myoglobin present on the outer surface of the meat. By limiting the amount of nitrite added to the beef, excess myoglobin in the beef is assured and no un-reacted nitrite will remain in the beef. Laboratory analyses conducted in accordance with FDA guidelines and using the best available analytical tests with a reliable detection limit of 0.7 ppm have found no nitrite in the packaged beef.^{6/} See Appendix 2.^{7/}

2. Nitric oxide

Virtually all of the sodium nitrite that diffuses from Bemis's packaging film into beef is converted to nitric oxide (NO). Nitric oxide is a very reactive compound, and it reacts immediately with myoglobin in the beef to produce nitrosomyoglobin. Nitric oxide's reactivity, combined with the excess amount of myoglobin present in the beef relative to the added sodium nitrite, makes it highly unlikely that any nitric oxide remains in the meat when the meat is consumed. After packaging and refrigerated storage for several days (*i.e.*, before and during delivery to the retail outlet), the amount of sodium nitrite in the film gradually decreases and the amount of nitrosomyoglobin in the vacuum-packaged beef gradually increases. After this time the characteristic color of raw beef is visually noticeable, suggesting that a sufficient amount of the myoglobin molecules in the surface regions of the meat tissue have been converted to nitrosomyoglobin. Once formed, nitrosomyoglobin complexes are extremely stable.^{8/}

Any small amounts of free nitric oxide that remain in the beef will be insignificant relative to the amount of nitric oxide already present in the body pool, and will be destroyed in the body when consumed. Nitric oxide is an important endogenous substance, synthesized by the human body from arginine, molecular oxygen, and nicotinamide adenine dinucleotide phosphate. Nitric oxide plays a physiological role in blood flow, kidney function, the nervous system and reproduction.

^{6/} The absence of sodium nitrite in beef packaged with Bemis's packaging film is not unexpected. For example, Cassens (1997) reported that only 10-20% of the ingoing sodium nitrite is present in nitrite-cured meats with much larger amounts of added nitrite (200-500 ppm). Cassens RG. (1997). "Residual Nitrite in Cured Meat." *Food Tech* 51(2): 53-55.

^{7/} Appendix 2 presents data demonstrating that when Bemis's film containing 105 mg of sodium nitrite per square meter of film was used to package ground beef and strip steaks, nitrite ion was not detectable in the beef until 36 days and 48 days after packaging, and the amount of nitrite ion measured was at or below the reliable detection limit of the analytical procedure (0.7 ppm). A description of the test protocol and analytical test method is provided at pp. 712-717 of Appendix 3.

^{8/} Giddings GG (1977). "Symposium: The Basis of Quality in Muscle Foods; The Basis of Color in Muscle Foods." *J Food Sci* 42(2): 288-294.

GRAS NOTIFICATION

Sodium Nitrite Added to Beef

Via Migration from Packaging Film

3. Nitrosomyoglobin

Nitrosomyoglobin (NOMb) begins to denature at temperatures of 40°C. Since cooking temperatures are much higher than 40°C, virtually all of the NOMb formed will be denatured. This will be the case even with beef cooked to a "rare" or "medium rare" state, since the NOMb is concentrated on the outer surface of the beef, which is the surface that is exposed to the highest temperatures. The key visual characteristic of nitrosomyoglobin is a reddish color, and the changed color of cooked beef is evidence that very little NOMb survives cooking. Any undenatured NOMb remaining in the consumed cooked beef will be digested and reduced to peptides and amino acids, just as would any other ingested and cooked protein.^{9/}

4. Nitrate

The only detectable substance remaining in raw beef packaged in Bemis's film is nitrate. Nitrate is an oxidation byproduct of nitrite that is present in the extremely low parts-per-million range. Samples of beef packaged in Bemis's packaging film have been analyzed and found to contain approximately 4.8 ppm nitrate ion, an amount that is approximately 2.0 ppm more than the amount of nitrate ion that occurs naturally in beef (*i.e.*, produced endogenously).^{10/} This small increase in nitrate content -- 2.0 ppm (equivalent to an intake of 0.01 mg/kg bw/day or 0.6 mg/p/day)^{11/} is well below the maximum contaminant level established for nitrate in drinking water (44 ppm), which the National Academy of Sciences (NAS) has concluded is adequate to protect human health.^{12/} It also is trivial when compared to the established ADI for nitrate of 3.7 mg/kg bw/day (222 mg/p/day) or to the typical daily amount of nitrate consumed in food, particularly green vegetables (62-124 mg/p/day) in the United States.^{13/}

Table 2 summarizes these observations.

^{9/} The denatured form of NOMb is nitrosohemochrome, and it will be present in the meat after cooking. However, the concentration of nitrosohemochrome in the finished product is a fraction of that present in cured meats, where ingoing nitrite levels are 50-100 times greater than those associated with the intended use that is the subject of this Notification.

^{10/} See Data presented in Appendix 2.

^{11/} $2.0 \text{ ppm} = 2 \text{ } \mu\text{g nitrate/g beef}$; $2 \text{ } \mu\text{g nitrate/g beef} \times 300 \text{ g beef} = 600 \text{ } \mu\text{g nitrate} = 0.6 \text{ mg nitrate/p/day}$ divided by 60 kg bw/p = 0.01 mg/kg bw/day.

^{12/} National Academy of Sciences (1995). "Nitrate and Nitrite in Drinking Water." National Academy Press (hereafter "NAS (1995)").

^{13/} Hotchkiss JH, Helser MA, Maragos CM, Weng YM (1992). "Nitrate, Nitrite and N-nitroso Compounds: Food safety and Biological Implications," in Food Safety Assessment, Finly JW, Robinson SF, Armstrong DJ (eds). Amer Chem Soc, pp 400-418.

Table 2
Maximum Concentration and Amounts
of Substances Added to and Present in Beef
(Amounts based on a 300 g Beef Portion)

Substance	Added Initially	Formed in Situ	Amount in Raw Beef
Sodium Nitrite (NaNO ₂)	2.19 mg sodium nitrite (1.46 mg nitrite ion) [0.0317 mmol]	0	2.19 mg sodium nitrite (1.46 mg nitrite ion) ^{14/} (0.0317 mmol)
Nitric Oxide (NO)	0	3.2 ppm [0.0317 mmol]	0
Nitrosomyoglobin (NOMb)	0	< 1,796 ppm (< 0.0317 mmol)	< 1,796 ppm (< 0.0317 mmol)
Nitrate (NO ₃)	0	< ~ 2.0 ppm (< 0.6 mg nitrate)	< ~ 2.0 ppm (< 0.6 mg nitrate)

- These calculations are based on a maximum film concentration of 113 mg/m² sodium nitrite and 100% migration as detailed in Table 1.
- The molecular weights are: 1) NaNO₂ = 69.01 Daltons, 2) NO = 30 Daltons, and 3) nitrosomyoglobin = ~17,000 Daltons.
- We assume each mole of NaNO₂ forms a mole of NO, which forms a mole of NOMb.
Calculation: 0.00219 g ÷ 69.01 g/mol = 0.0000317 mol = 0.0317 mmol
- The amount of nitrate present in the beef has been experimentally determined. See Appendix 2.

^{14/} As indicated above, the amount of nitrite remaining in the meat has been measured using an analytical method with a detection limit of 0.7 ppm, and no nitrite was detected. However, our sodium nitrite intake calculations use a 100% migration factor, which yields a daily intake of 2.19 mg of sodium nitrite or 1.46 mg of nitrite ion. Using Bemis's analytical measurements, and assuming that meat packaged in Bemis's film contains nitrite at a level of one half the detection limit (0.35 ppm), a daily dietary intake of 0.105 mg of nitrite ion can reasonably be expected (300 g beef/day x 0.35 µg nitrite ion/g beef = 0.105 mg nitrite ion). The Bemis data corroborates the safety and GRAS status of the Company's intended use of sodium nitrite.

C. Safety of Added Nitrite

1. Existing Regulations Permit Added Nitrite in Food

While the existence of related, FDA-issued food additive regulations authorizing the use of sodium nitrite in food is not, by itself, sufficient to establish GRAS status, it is appropriate to consider such approvals when evaluating the safety of the proposed use of nitrite in vacuum packaging film. In the present case, such clearances are both relevant and material because (a) existing regulations approve the use of sodium nitrite in food at amounts that substantially exceed the exposures anticipated in the proposed use, and (b) the proposed use is not anticipated to add significantly to total dietary exposure to nitrite.

Below is a list of current FDA clearances for sodium nitrite added directly to food:

- 21 C.F.R. § 172.175 (Sodium nitrite as a color fixative in smoked tuna products at ≤ 10 ppm in the finished food; as a preservative and color fixative in smoked, cured sablefish, salmon and shad at ≤ 200 ppm in the finished food; as a preservative and color fixative in use-at-home meat and meat product curing preparations (including poultry and wild game) at ≤ 200 ppm in the finished food);
- 21 C.F.R. § 172.177 (Sodium nitrite as an ingredient in processing smoked chub at levels ≥ 100 ppm and ≤ 200 ppm in the finished food);
- 21 C.F.R. § 170.60(b) (Nitrite as an ingredient in meat curing premixes when packaged separately from seasoning and flavoring ingredients); and
- 21 C.F.R. § 573.700 (Sodium nitrite as a preservative and color fixative in canned pet food containing fish and/or meat at levels < 20 ppm in the finished pet food).

As indicated above, a maximum of 2.19 mg of sodium nitrite (equivalent to 1.46 mg of nitrite ion) will be added to a 300 gram portion of beef as a result of the proposed use of Bemis's vacuum packaging film. This is equivalent to 7.3 ppm of sodium nitrite (4.87 ppm of nitrite ion) in the finished food. The proposed use level is clearly well below each of these previously approved uses. In addition to these clearances, many regulations authorize the use of sodium nitrite in food-contact applications.^{15/}

^{15/} See, e.g., 21 C.F.R. §175.105 (Adhesives); 21 C.F.R. §175.300(b)(3)(xxxi) (Resinous and polymeric coatings); 21 C.F.R. §§176.170 and 176.180 (Components of paper and paperboard in contact with aqueous and fatty foods; . . . in contact with dry food); 21 C.F.R. § 177.1210 (Closures with sealing gaskets for food containers); 21 C.F.R. § 177.2600 (Rubber articles intended for repeated use); 21 C.F.R. § 178.3570 (Lubricants with incidental food contact); and 21 C.F.R. §178.3910 (Surface lubricants used in the manufacture of metallic articles).

GRAS NOTIFICATION

Sodium Nitrite Added to Beef

Via Migration from Packaging Film

2. Scientific Studies on Nitrite Safety

a. *Absorption, Distribution and Elimination*

Nitrite ingested in small amounts is absorbed directly in the stomach. When administered in larger amounts some nitrite passes into the lower intestine where it is absorbed by the body. In either case, absorption following ingestion is essentially complete.^{16/} The half-life for stomach absorption in rats is approximately 5-10 minutes, a process aided by the oxidation of nitrite to nitrate, the latter being absorbed more rapidly.^{17/} When administered intratracheally or by intravenous injection, both nitrite and nitrate distribute widely and equally in the same body space.^{18/} The main fate of nitrite in blood is the rapid reaction with hemoglobin to yield methemoglobin. The normal amount of methemoglobin in human blood is reported to be between 0.5% and 2.5% of total hemoglobin.^{19/} Nitrite administered to mature ewes in doses of 6.6, 22, 35, or 50 mg/kg bw resulted in maximum methemoglobin levels of 13% at 15 min, 43% at 45 min, 63% at 60 min and 80% just before death.^{20/} The reaction with hemoglobin is so rapid that little nitrite is transported to the tissues.^{21/} Nitrite is so reactive that essentially none remains to be excreted; some is converted to nitrate and excreted by the kidneys.^{22/}

b. *Acute Toxicity*

In perhaps the seminal study on the acute toxicity of nitrite, A J Lehman determined that the oral LD50 for sodium nitrite in rats is 85 mg/kg bw and in mice it ranges from 175-220 mg/kg bw.^{23/} Clinical signs of acute nitrite intoxication in rodents included vasodilation, lowering of blood pressure, decrease in vitamin A content of the liver, and functional disturbance of the thyroid gland.

The principal adverse effect associated with human exposure to nitrite is methemoglobinemia, where nitrite converts hemoglobin to methemoglobin by oxidizing the Fe⁺²

^{16/} EPA (1990). "The Drinking Water Criteria Document on Nitrate/Nitrite." Doc. # TR-1242-60B at I-1, III-18. Prepared for Criteria and Standards Division, Office of Drinking Water, Environmental Protection Agency. December 21, 1990. NTIS Publication (hereafter "EPA Drinking Water Document").

^{17/} *Id.*, pp. III-1-3.

^{18/} *Id.*, p. III-5.

^{19/} *Id.*, p. III-10.

^{20/} Burrows GE, Way JL (1979). "Cyanide Intoxication in Sheep; Enhancement of Efficacy of Sodium Nitrite, Sodium Thiosulfate, and Cobaltous Chloride." *Am J Vet Res* 40(5): 613-617, as cited in EPA Drinking Water Document, p. III-10.

^{21/} EPA Drinking Water Document, p. I-2.

^{22/} *Id.*

^{23/} Lehman AJ (1958). "Nitrates and Nitrites in Meat Products." *Quarterly Bulletin of the Assoc of Food & Drug Officials*; 22: 136-138.

GRAS NOTIFICATION

Sodium Nitrite Added to Beef

Via Migration from Packaging Film

ion to the ferric state Fe^{+3} .^{24/} Methemoglobin is not capable of carrying or transporting oxygen and, if formed to a sufficient extent, oxygen delivery to body tissues can be impaired. The United States Environmental Protection Agency (EPA) has established a Reference Dose (RfD) for nitrite in human infants of 0.16 mg of nitrogen/kg bw/day, which is equivalent to 0.53 mg/kg bw/day on a nitrite ion basis.^{25/} Extrapolating to adults yields an ADI of 31 mg of nitrite/day for a 60 kg individual.

c. Reproductive Toxicity

FDA has sponsored extensive studies of sodium nitrite and potassium nitrite in mice, rabbits, and rats. These studies reported No Observed Adverse Effect Levels (NOAELs) for the reproductive toxicity of nitrite ion as 17.4 mg/kg bw/day in mice; 15.1 mg/kg bw/day in rabbits, and 6.6 mg/kg bw/day in rats.^{26/} In 1997, Chapin *et al* demonstrated that sodium nitrite had no adverse effect on reproductive performance in mice treated with doses up to 420 mg/kg bw/day.^{27/} Teratogenic effects were not observed in reported studies in rats at doses up to 120 mg/kg bw/day of potassium nitrite.^{28/}

d. Mutagenicity

Studies have confirmed that nitrite is genotoxic in *in vitro* bacterial assays without metabolic activation, probably due to deamination of DNA bases at the high concentrations evaluated in the studies. Intraperitoneal injection of sodium nitrite in male mice and rats did not induce micronuclei formation in bone marrow.^{29/} *In vivo* assays are equivocal and the mutagenic potential of nitrite is complicated by the potential endogenous transformation to N-nitroso compounds when both nitrite and N-nitrosatable compounds are present at high concentrations. In the present case, however, the added nitrite is virtually destroyed in the production of nitric oxide and nitrosomyoglobin, and the corresponding levels of added nitrate are 2.0 ppm or less; accordingly, there is no significant cancer hazard from Bemis's packaging film.

^{24/} EPA Drinking Water Document, p. I-3.

^{25/} EPA Drinking Water Document, p. VIII-16.

^{26/} Food and Drug Research Laboratories, Inc. (1972). "Teratologic Evaluation of FDA 71-9 (Sodium Nitrite)." Maspeth, NY: FDA Contract FDA-71-260, Rept. No. FDABF-GRAS-061; and Food and Drug Research Laboratories, Inc. (1972). "Teratologic Evaluation of FDA 71-10 (Potassium Nitrite)." Maspeth, NY: FDA Contract FDA-71-260, Rept. No. FDARF-GRAS-065; as cited in EPA Drinking Water Document, p. V-20.

^{27/} Chapin R, Gulati D & Barnes LH (1997). "Reproductive Toxicology; Sodium Nitrite." *Environ Health Perspect*, 105(Supp 1): 1-3.

^{28/} Shiobara S. (1987). "Effects of Sodium Nitrite ($NaNO_2$) Administration on Pregnant Mice and Their Fetuses." *Jpn J Hyg* 42(4): 836-846, as cited in EPA Drinking Water Document, p. V-26.

^{29/} National Toxicology Program (2001). "Toxicology and Carcinogenesis Studies of Sodium Nitrite (CAS No. 7632-00-0) in Fischer 344/N and B6C3F1 Mice (Drinking Water Studies)." Research Triangle Park, North Carolina, Department of Health and Human Services, Public Health Services, National Institutes of Health.

GRAS NOTIFICATION

Sodium Nitrite Added to Beef

Via Migration from Packaging Film

3. Reviews of Nitrite by Scientific Organizations

Various scientific groups have reviewed the safety of nitrite intake over the years. One such group is the Joint FAO/WHO Expert Committee on Food Additives (JECFA), which periodically reviews the available toxicity data on food substances. JECFA has reviewed the safety and toxicological data on nitrite a total of five times, with the most recent review occurring in 2003.^{30/} The effects of continuous administration of nitrite to experimental animals include vasodilation and sedation, methemoglobinemia and histological changes in cardiac muscle, lung, liver, spleen, kidney and adrenals. In 1995, JECFA noted the hypertrophy of adrenal zona glomerulosa in the rat as the most sensitive endpoint and identified the NOEL as 5.4 mg/kg bw per day (expressed as nitrite ion).^{31/} At its 59th meeting in 2003, however, JECFA concluded that its previously established NOEL of 5.4 mg/kg bw per day was no longer relevant, as it was demonstrated to be an adaptation to small fluctuations in blood pressure and therefore should not be considered a direct toxic action on the adrenals.^{32/} In 2003, JECFA identified a NOEL of 6.7 mg/kg bw per day in a 2-year study in rats, in which effects on the heart and lungs were observed at the next higher dose. On the basis of this higher NOEL, and utilizing a safety factor of 100, the Committee established an Acceptable Daily Intake (ADI) for nitrite ion of 0-0.07 mg/kg bw.^{33/}

In 1995, the EU Scientific Committee for Food (SCF) reviewed the toxicology data on nitrite and affirmed the adrenal hypertrophy found in adrenal cells in the rat in the 13 week Til *et al* 1988 study as the most sensitive effect.^{34/} The NOEL for this effect was given as 10 mg of potassium nitrite/kg bw/day (equivalent to 5.4 mg nitrite ion/kg bw/day.) Noting the earlier 2-year rat study on sodium nitrite, which demonstrated a NOEL of 6.7 mg nitrite ion/kg bw/day, the SCF rounded the ADI on nitrite ion to 0.06 mg/kg bw/day (based on a 100-fold safety factor).^{35/} This is essentially the same ADI as JECFA's latest (2003) determination, although the reasoning is slightly different.

^{30/} Joint FAO/WHO Expert Committee on Food Additives (JECFA), 59th Meeting (2003). "Nitrite (and Potential Endogenous Formation of N-nitroso Compounds)," in Safety Evaluation of Certain Food Additives, WHO Food Additive Series No. 50 (hereafter "JECFA, 59th Meeting (2003)"). Also see Til HP, Falke HE, Kuper CF, Willems MI (1988). "Evaluation of the Oral Toxicity of Potassium Nitrite in a 13-week Drinking Water Study in Rats." *Food Chem Toxic* 26: 851-859 (hereafter "Til *et al* (1988)"); and see Shuval HI and Gruener N. (1972). "Epidemiological and Toxicological Aspects of Nitrates and Nitrites in the Environment." *Am J Pub Health* 62: 1045-1052.

^{31/} JECFA, 44th Meeting (1995). "Nitrite (and Potential Endogenous Formation of N-Nitroso Compounds)," in Toxicological Evaluation of Certain Food Additives and Contaminants in Food. Food Additive Series 35 (hereafter "JECFA, 44th Meeting (1995)").

^{32/} JECFA, 59th Meeting (2003).

^{33/} *Id.*

^{34/} Reports of the Scientific Committee for Food (SCF), 38th Series (1997). "Opinion on Nitrate and Nitrite (expressed on 22 September 1995)" (hereafter "SCF Report (1995)").

^{35/} *Id* at p.20

GRAS NOTIFICATION

Sodium Nitrite Added to Beef

Via Migration from Packaging Film

EPA's evaluation in 1990 did not have the benefit of Til *et al*'s 1990 paper or the additional 1997 paper by Til *et al*. EPA also concluded that the adrenal changes reported in the 1988 Til *et al* study were a normal adaptive response to a change in blood volume due to decreased water intake. EPA noted that (1) the toxicity of nitrate was due to its endogenous conversion to nitrite, and (2) that the ability of nitrite to react with hemoglobin to form methemoglobin was the most sensitive human effect. In particular, this effect was more sensitive in human infants than in animals, so that animal extrapolation of the effect was not prudent. EPA therefore chose to calculate the safe level for nitrite toxicity in humans by extrapolation of the highly reliable nitrate toxicity data in human infants to nitrite toxicity in human infants. To do this EPA assumed a 10% conversion rate for nitrate-to-nitrite in infants. The human data on nitrate-induced methemoglobinemia consisted of approximately 10 different studies all showing NOELs in the range of 5.3-18.0 mg of nitrate ion/kg bw/day. Using the 10% conversion factor, the lowest NOEL for nitrite ion *per se* was determined to be 0.53 mg/kg bw/day. Since the data was already on the most susceptible group (human infants), EPA did not apply a safety factor to this NOEL. It is primarily for this reason that the SCF's and EPA's ADIs for nitrite differ by approximately 10-fold.

Table 3 summarizes the ADIs for nitrite established by various scientific bodies and the technical data relied upon by these bodies in their determinations.

Table 3
ADIs for Nitrite Ion (NO₂⁻)

Agency	ADI (Nitrite Ion Basis)	Study Author	Safety Factor	Toxicological Endpoint
JECFA (2003)	0.07 mg/kg bw/day or 4.2 mg/day	Shuval and Gruener (1972) ^{36/}	100	Heart and lung histology in rats
EU SCF (1995)	0.06 mg/kg bw/day or 3.6 mg/day	Til <i>et al</i> (1988), Til <i>et al</i> (1990), and Til & Kuper (1995) ^{37/}	100	Hypertrophy of adrenal cells in rats.
US EPA (1990)	0.53 mg/kg bw/day* or 31.8 mg/day	Bosch <i>et al</i> (1950), <i>also</i> Walton (1951) ^{38/}	1.0	Methemoglobinemia in infants.

*EPA's value is reported as 0.16 mg/kg bw/day on a Nitrogen (N) basis. To convert to a Nitrite ion basis, divide by 0.304. ADI (NO₂⁻ basis) = 0.16/0.304 = 0.53 mg/kg bw/day.

Since JECFA reviewed the safety and toxicological data on nitrite most recently (by at least eight years), and it reviewed data that was not available to the EU SCF and the US EPA when they conducted their reviews, we rely upon JECFA's most recent evaluation of nitrite and its ADI of 0.07 mg/kg bw/day (equivalent to 4.2 mg nitrite/day for a 60 kg adult) as the basis for our exposure calculations.

^{36/} *Infra.*

^{37/} Til *et al* (1988); Til HP, Falke HE & Kuper CF (1990). "Supplementary subchronic (90-day) Toxicity Study of Nitrite Administered to Rats in the Drinking Water." TNO Report, V90.271, Zeist; and Til HP & Kuper CF (1995). "Subchronic Toxicity Experiments with Potassium Nitrite in Rats." Proceedings of the International Workshop on Health Aspects of Nitrate and its Metabolites (Particularly Nitrite). Bilthoven (Netherlands) 8-10 November 1994. Council of Europe Press, Strasburg.

^{38/} Bosch HM, Rosefield AB *et al* (1950). J Amer Water Works Assoc. 42: 161, cited in Simon C, Manzke H, *et al* (1964) "Uber Vorkommen, Pathogenese und Moglichkeiten zur Prophylaxe der durch Nitrit verursachten Methhamoblobinamie. Z. Kinderheilkd. 91: 124-138 (In German, summary in English); and Walton G (1951). "Survey of Literature Relating to Infant Methemoglobinemia Induced by Sodium Nitrite." J Clin Investi 16: 73-84.

GRAS NOTIFICATION

Sodium Nitrite Added to Beef

Via Migration from Packaging Film

4. Exposure to Nitrite from Nitrate Metabolism and Nitrate-Containing Foods

a. *Endogenous Production of Nitrite from Dietary Nitrate*

A relatively constant, daily endogenous production of about 1.0 mmol of nitrate (equivalent to 62 mg of nitrate or approximately 1.0 mg/kg bw/day) in the human body was established by Wishook *et al* in 1995.^{39/} A major pathway for endogenous nitrate production is the conversion of arginine to nitric oxide and citrulline followed by oxidation to nitrogen oxide and then reaction with water to yield nitrite, which is rapidly oxidized to yield nitrate. The amount of residual, circulating nitrite from this source is unknown.

The principal sources of dietary nitrate are green vegetables. Vegetables rich in nitrate include celery (870-3,700 ppm), green beans (195-450 ppm), beet root (1,560-2,590 ppm), chard (2,080 ppm), cabbage (150-1,600 ppm), broccoli (125-470 ppm), lettuce (140-4,670 ppm) and spinach (390-3,380 ppm).^{40/} Most recent estimates of nitrate intake in European countries range from 52-156 mg/day.^{41/} Vegetarians in the UK had levels between 185-195 mg/day, four times the national average.^{42/} The National Academies of Science has assumed an average adult intake of 75 mg nitrate/day for the US from all sources.^{43/} EPA has assumed that no more than 10% of this nitrate is converted to nitrite by saliva in infants and no less than 5% in adults, giving a nitrite formation rate of $75 \times 0.05 = 3.75$ mg nitrite/day for adults.^{44/}

b. *Exposure to Nitrite from Dietary Nitrite*

The major dietary sources of nitrite intake are cured meats, fish and vegetables. Estimates of the daily intake of added nitrite from all food groups ranges from 0.7-4.2 mg/day. The EU SCF recognizes the higher value as an overestimate as a result of the methodology used.^{45/} We have used a dietary intake value of 2.0 mg/day as a conservative estimate.

By combining these two values, *i.e.*, the amount of nitrite formed endogenously from ingested nitrate and the amount of nitrite ingested from the diet, the daily exposure to nitrite can be calculated to be approximately 5.75 mg/day ($3.75 \text{ mg/day} + 2.0 \text{ mg/day} = 5.75 \text{ mg/day}$).

^{39/} Wishook JS, Tannenbaum SR, Tamir S, and De Rojas-Walker T. (1995). "Endogenous Formation of Nitrate." Proceedings of the International Workshop on Health Aspects of Nitrate and its Metabolites (Particularly Nitrite). Bilthoven (Netherlands), 8-10 November 1994. Council of Europe Press, Strasbourg.

^{40/} SCF Report (1995), p. 7.

^{41/} SCF Report (1995), p. 9.

^{42/} *Id.*

^{43/} NAS (1995).

^{44/} National Academy of Sciences (1981). "The Health Effects of Nitrate, Nitrite and N-nitroso Compounds." Washington, DC. National Academy Press, as cited in EPA Drinking Water Document, pp. VIII-15,16; also EPA Drinking Water Document, pp. I-2, III-19.

^{45/} SCF Report (1995), p. 11.

c. *Exposure to Nitrite from Bemis's Packaging Film*

As noted above, Bemis Company's packaging film contains a maximum of 113 mg of sodium nitrite per square meter of packaging film. The sodium nitrite diffuses onto the beef where it forms nitric oxide, which reacts with the meat myoglobin to form nitrosomyoglobin, which maintains the characteristic color of vacuum packaged raw beef. The calculations above in Section III.1 demonstrate that if all of the sodium nitrite in the film were to diffuse into a 300 gram portion of beef, and no reducing reactions occur, the total amount of sodium nitrite in the beef will be 2.19 mg, which is equivalent to a daily intake of 1.46 mg of nitrite ion.

5. The Amount of Dietary Nitrite from Bemis's Packaging Film is Trivial, Safe, and GRAS

The maximum nitrite ion intake of 1.46 mg/day from the proposed use is roughly 65% less than the 4.2 mg/day ADI that JECFA has established for nitrite ion based on published studies. This amount (1.46 mg/day) is also much less than the amount of nitrite produced endogenously from ingested nitrate and ingested from other nitrite sources, such as vegetables and cured meats and fish (5.75 mg/p/day).

Furthermore, when the actual proposed conditions of use are considered, *i.e.*:

- (1) There is no measurable nitrite ion in beef packaged in Bemis film when tested with an analytical method with a limit of detection of 0.7 ppm, and
- (2) Virtually all of the added sodium nitrite is converted in the beef to nitric oxide, and then to nitrosomyoglobin, which ensures an extremely low level of residual nitrite ion,

it is clear that the amount of nitrite ion proposed to be added to the diet from Bemis's packaging film not only is far less than the worst case estimate calculated above, but essentially trivial. There is no conceivable risk to human health from the proposed use of sodium nitrite.

6. Safety Studies on Nitrate

Numerous scientific studies have evaluated the safety of nitrate, and on the bases of these studies, scientists consider nitrate to be of relatively low toxicity. The key safety study demonstrating the safety of nitrate intake is the 1958 study by A. J. Lehman.^{46/} In the Lehman study, rats were fed a diet containing 0, 0.1, 1, 5 or 10% nitrate for a 2 year period. The study demonstrated a NOEL for nitrate of 1%. At the 5% intake level a slight growth inhibition was observed, whereas inanition was noticed at the 10% intake level. A complete histological examination was performed, including a determination of tumor incidences, and no abnormalities or increased frequency of tumor incidences were found. The NOEL of 1% is equivalent to a nitrate ion intake of 370 mg/kg bw/day, which correlates to a human dietary nitrate intake of 3.7 mg/kg bw/day after a safety factor of 100 is applied.

Over the past two decades, JECFA has reviewed numerous scientific studies evaluating the safety of sodium nitrate, including the Lehman study discussed *infra*. On the basis of its consideration of these studies, JECFA established an ADI for nitrate ion of 0-3.7 mg/kg bw, which is equivalent to a sodium nitrate intake of up to 300 mg/p/day for a typical adult.^{47/}

IV. Reports of Investigations Inconsistent with GRAS Status

We are unaware of any reports, investigations or other information that are inconsistent with the GRAS status of the proposed use of Bemis Company's packaging film to deliver small amounts of sodium nitrite to the surface of raw ground beef and raw whole muscle cuts of beef.

^{46/} Lehman AJ (1958). "Nitrates and Nitrites in Meat Products." Quarterly Bulletin of the Assoc of Food & Drug Officials; 22: 136-138.

^{47/} JEFCA, 44th Meeting (1995). The nitrate ion ADI of 0-3.7 mg/kg bw or 222 mg/p/day (3.7 mg/kg x 60 kg = 222 mg) is equivalent to an ADI for sodium nitrate of 0-5 mg/kg bw (1.37 x 3.7 = 5) or 300 mg/p/day (5 mg/kg x 60 kg = 300 mg).

GRAS NOTIFICATION

Sodium Nitrite Added to Beef

Via Migration from Packaging Film

V. Functionality

A. **The Added Sodium Nitrite is Effective at Maintaining The Color of Raw Beef While In the Vacuum Package**

The color of raw ground beef and raw whole muscle cuts of beef packaged in Bemis's packaging film was compared to the color of similar raw beef products packaged in plain packaging film in experiments using the CIE L*a*b* (CIELAB) color evaluation model. The CIELAB color evaluation model is the most complete color model used conventionally to describe all of the colors visible to the human eye. It was developed for this purpose by the International Commission on Illumination (*Commission Internationale d'Eclairage*, hence its *CIE* initials). CIELAB measures three parameters: L*, a*, and b*, with L* representing the lightness of the sample color (L* = 0 represents black, while L* = 100 indicates white), a* representing the sample color's position between magenta and green (negative a* values indicate green and positive a* values indicate magenta), and b* representing the sample color's position between yellow and blue (negative b* values indicate blue and positive b* values indicate yellow).

The experiments assessed the color of beef products when they were still in the vacuum package. The results of the experiments indicate that, while the beef is still in the vacuum package, and regardless of the age of the beef prior to packaging, storage time, and the type of beef product evaluated (*e.g.*, ground beef or strip steak), beef products vacuum packaged in Bemis's film demonstrated the characteristic color of raw beef. Accordingly, Bemis's film is effective at helping to maintain the characteristic color of raw beef while the beef is in the vacuum packaging. Photographs and data demonstrating this effect on color maintenance are included in Appendix 4.

B. **Once Removed from the Package, Beef Packaged in Sodium Nitrite-Containing Film Fades to a Duller Color than Beef Packaged in Plain Film**

In addition to assessing color while the beef products were still in their packaging, the experiment also assessed the beef products' color at multiple endpoints after removal from the packaging. Three particularly relevant endpoints were 1) 10 minutes post-opening, 2) 45 minutes post-opening, and 3) approximately 21 hours after the beef was removed from the vacuum packaging. At each of these endpoints, the inverse color presentation was observed, *i.e.*, the beef packaged in plain film exhibited a brighter color than the beef packaged in Bemis's film.

This data indicates that the color of beef packaged in sodium nitrite-containing film fades after removal from the package, and when compared to the identical product vacuum packaged in plain film, exhibited a duller color. Since beef vacuum packaged in plain film exhibits a brighter red color than beef vacuum packaged in Bemis's film after the products are removed from the packaging, consumers are unlikely to rely inappropriately on the beef's color as an indicator of quality. Photographs and data demonstrating that, after removal from the package, the color of beef with added sodium nitrite fades to a duller color than beef packaged in plain film are included in Appendix 4.

C. The Amount of Sodium Nitrite Added is the Minimum Amount Needed

Bemis Company has determined that the characteristic color of raw beef can be maintained by nitrosylating only a portion of the myoglobin on the meat's surface, rather than all of the myoglobin in the meat. The calculations below demonstrate that, on a molar basis, the amount of sodium nitrite added to, and nitric oxide produced on, the beef's surface is less than the amount of myoglobin present in the beef.

Practical cuts of beef typically contain 4-10 milligrams of myoglobin per gram of meat (mg/g).^{48/} To be conservative, our calculations below consider the molar concentration of myoglobin in the lighter colored beef, which is approximately 0.235 $\mu\text{mol/g}$ ($4 \text{ mg/g} = 4,000 \mu\text{g/g} \div 17,000 \text{ g/mol} = 0.235 \mu\text{mol/g}$). The corresponding theoretical molar concentration of nitric oxide in the meat (formed from the added sodium nitrite) is 0.106 $\mu\text{mol/g}$ ($0.0317 \text{ mmol} \div 300 \text{ g} = 1.06 \times 10^{-4} \text{ mmol/g} = 0.106 \mu\text{mol/g}$), or approximately 55% less. A comparison of the molar amounts of myoglobin (0.235 $\mu\text{mol/g}$) and added sodium nitrite (0.106 $\mu\text{mol/g}$) demonstrates that the amount of myoglobin is in stoichiometric excess when compared to the amount of nitric oxide formed in the meat. Clearly, a significant amount of myoglobin is remaining in the meat, unreacted with nitric oxide. Bemis has designed its packaging film to deliver only the minimum amount of sodium nitrite necessary to maintain the characteristic color of raw vacuum packaged beef, which is well below the amount of nitrite that would be needed to nitrosylate all of the myoglobin present in the meat.

VI. Labeling

The labels of beef products packaged in Bemis's film will bear an ingredient statement that declares the presence of sodium nitrite in the packaging film. Thus, its addition to the food will be clearly conveyed to consumers at the point of purchase.

Additionally, the labels of beef products packaged in Bemis's film will bear a "Use by (date)" or "Freeze by (date)" statement that will communicate to the consumer the product's shelf life. Just as when such Use by/Freeze by date labeling is used on conventionally packaged meat products, the date indicated on the product label will reflect the last date by which the product can be consumed or frozen and still be wholesome.

Finally, the labels of beef products packaged in Bemis's film will bear appropriate cooking and handling directions indicating that the beef should be cooked to an appropriate temperature and not to use meat color as an indicator of doneness. These label statements will ensure that consumers do not rely unreasonably upon the beef product's color as an indicator of freshness to the detriment of other freshness and quality indicators, such as the lack of odor or slime formation, which are the same characteristics consumers of cured meats use to evaluate freshness.

^{48/} Kramlich, WE, Pearson AM, Tauber, FW (1973). Processed Meats (1st ed), p. 47. AVI Publishing Co., Westport, CT.

GRAS NOTIFICATION

Sodium Nitrite Added to Beef

Via Migration from Packaging Film

VII. Conclusion: Sodium Nitrite Added to Raw Beef Products via Migration from Bemis's Vacuum Packaging Film is GRAS

The studies, analytical data, and information presented above demonstrate the basis of the Notifier's position that the proposed use of Bemis's vacuum packaging film to package raw ground beef and raw whole muscle cuts of beef poses no health hazard to the consumer. The levels of ingested nitrite and nitrate are trivial and are well below the established ADIs for nitrite and nitrate. Furthermore, the level of sodium nitrite added to beef by the proposed use is many times less than the levels of sodium nitrite currently allowed in cured meat applications. Finally, toxicity data establishing the safe intake of nitrite and nitrate are abundant, have been published in the scientific literature and subjected to peer review, and are accepted by well-established, science-based health and safety organizations in the United States and Europe such as FDA, JECFA, and SCF.

The other related substances potentially present in meat packaged in Bemis's film are nitric oxide, which is endogenous in the human body and trivial in amount when compared to the amount in the body pool, and myoglobin pigments, which are metabolized in the same way as natural myoglobin pigments. Additionally, ingredient listing, "Use by/Freeze by" statements, and cooking and handling instructions will appear on product labels to ensure that customers are clearly informed (a) of the sodium nitrite in the packaging film, (b) of the date by which the product should be used or frozen for optimum quality and wholesomeness, and (c) to rely on indicators other than color when evaluating freshness.

* * *

In light of the data and information presented above and in the attached Appendices, Bemis Company has concluded that there is a consensus, among experts qualified by scientific training and experience to evaluate the safety of substances added to food, that there is a reasonable certainty that sodium nitrite added to raw ground beef and raw whole muscle cuts of beef via migration from sodium nitrite-containing packaging film, under the intended conditions of use outlined above, is both safe and generally recognized as safe and therefore exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act.

Pages - have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

Material Safety Data Sheet

SODIUM NITRITE HIGH PURITY GRANULAR

Page 1 of 6

Revised 2005-01-10 11:21:45

Replaces 2002-10-22 13:53:27

As of 2006-07-19 00:27:32

MSDS ID: NA1402

1. PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME : SODIUM NITRITE HIGH PURITY GRANULAR
MSDS ID : NA1402
CHEMICAL NAME SYNONYMS : Nitrous acid, sodium salt
CAS NUMBER : 7632-00-0
CHEMICAL FAMILY : Inorganic Salt
FORMULA : NaNO₂

*Sodium Nitrite
USP Granular*

DISTRIBUTED BY:
Hydrite Chemical Co.
300 N. Patrick Blvd.
Brookfield, WI 53008-0948
(262) 792-1450

EMERGENCY RESPONSE NUMBERS:
24 Hour Emergency # - (414) 277-1311
CHEMTREC Emergency # - (800) 424-9300

MANUFACTURED BY: General Chemical

2. COMPOSITION/INFORMATION ON INGREDIENTS

COMPONENT	CAS NUMBER	OSHA HAZARD	% BY WT.
Sodium Nitrite	7632-00-0	YES	> 95 %

3. HAZARDS IDENTIFICATION

PHYSICAL STATE: Crystalline powder.
COLOR : White to pale yellow.
ODOR : No odor.

EMERGENCY OVERVIEW: Oxidizer!; May ignite organic materials and react with other materials. Harmful if swallowed. Harmful if inhaled. May cause eye, skin and respiratory irritation.

POTENTIAL HEALTH EFFECTS

ROUTES OF EXPOSURE:
Eyes. Ingestion. Inhalation. Skin.

TARGET ORGANS:
None Known.

EYE CONTACT:
May cause severe irritation.

SKIN CONTACT:
May cause mechanical irritation.

SKIN ABSORPTION:
No data available.

INHALATION:
May cause mechanical irritation.
Harmful if inhaled. Dusts may irritate: nose, throat, respiratory tract.
Dusts are soluble. May produce signs and symptoms of toxicity similar to those described for swallowing. Inhalation of large amounts of mist may cause: central nervous system effects, visual disturbances, mental disturbances.

INGESTION:
May cause moderate irritation.



Material Safety Data Sheet

SODIUM NITRITE HIGH PURITY GRANULAR

Page 2 of 6

Revised 2005-01-10 11:21:45

Replaces 2002-10-22 13:53:27

As of 2006-07-19 00:27:32

MSDS ID: NA1402

Harmful if swallowed. May cause irritation of the: mouth. esophagus. stomach. Moderate amounts may cause: nausea. vomiting. weakness. methemoglobin formation. cyanosis. convulsions. collapse. coma. death. Intentional ingestion of high doses have been reported to produce salivation, vomiting, burning sensation, severe pain, metabolic acidosis, blindness and even death.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE TO PRODUCT:

None known.

OTHER:

Chronic exposure to nitrites may cause headaches, visual problems, and decreased blood pressure. Nitrites may react with secondary and tertiary amines to form nitrosamines, which are animal carcinogens. Due to the possibility of nitrosamine formation, sodium nitrite is not to be used in metalworking fluids containing amines.

CANCER INFORMATION:

This product does not contain greater than 0.1% of the known or potential carcinogens listed in NTP, IARC, or OSHA.

POTENTIAL ENVIRONMENTAL EFFECTS:

See Section 12.

4. FIRST AID MEASURES

EYE CONTACT:

Immediately flush eyes with plenty of water for at least 15 minutes while holding eyelids open. Tilt head to avoid contaminating unaffected eye. Get immediate medical attention.

SKIN CONTACT:

Flush skin with plenty of water while removing contaminated clothing and shoes. Do not reuse clothing or shoes until cleaned. If irritation develops or persists, get medical attention.
Wash with soap and water.

INHALATION:

Remove to fresh air. If breathing is difficult, administer oxygen. If not breathing, give artificial respiration, preferably mouth-to-mouth. GET MEDICAL ATTENTION IMMEDIATELY.

INGESTION:

If fully conscious, give two glasses of water, then induce vomiting by touching back of throat with finger. Keep head below hips to prevent aspiration of liquid into the lungs. CALL A PHYSICIAN immediately. Never induce vomiting or give anything by mouth to an unconscious victim.

NOTE TO PHYSICIANS: Sodium nitrite forms methemoglobin in the blood stream. Treat accordingly.

5. FIRE FIGHTING MEASURES

FLASH POINT: N.A.

FLAMMABILITY LIMITS: LEL: N.A.

UEL: N.A.

AUTOIGNITION TEMPERATURE: N.A.

EXTINGUISHING MEDIA:

Material Safety Data Sheet

SODIUM NITRITE HIGH PURITY GRANULAR

Page 3 of 6

Revised 2005-01-10 11:21:45

Replaces 2002-10-22 13:53:27

As of 2006-07-19 00:27:32

MSDS ID: NA1402

Carbon dioxide. Foam. Water fog. Use flooding amounts of water in early stages of fire. However, when large quantities are involved, nitrite may fuse or melt, in which condition, application of water may cause extensive scattering of molten material. DO NOT USE: Dry chemical extinguisher containing ammonium compounds.

FIRE FIGHTING METHODS:

Evacuate area of unprotected personnel. Wear protective clothing including NIOSH-approved self-contained breathing apparatus. Remain upwind of fire to avoid hazardous vapors and decomposition products. Use water spray to cool fire-exposed containers.
Run-off from fire control may cause pollution.

FIRE AND EXPLOSION HAZARDS:

STRONG OXIDIZER.

Material does not burn but is an oxidizing agent and will support combustion of other materials. Contact with organic or combustible material may cause fire. Material explodes when heated to 1000 Deg. F. or upon contact with cyanides.

HAZARDOUS COMBUSTION PRODUCTS:

At elevated temperatures, product will decompose generating: Nitrogen oxides.

6. ACCIDENTAL RELEASE MEASURES

SPILL CLEAN-UP PROCEDURES:

STRONG OXIDIZER. Eliminate all sources of ignition. Evacuate unprotected personnel from area. Maintain adequate ventilation. Follow personal protective equipment recommendations found in Section 8. Never exceed any occupational exposure limit.

Sweep up material into containers and dispose of properly. Avoid dust formation. Flush remaining area with water to remove trace residue and dispose of properly. Avoid direct discharge to sewers and surface waters. Notify authorities if entry occurs.

7. HANDLING AND STORAGE

STORAGE:

STRONG OXIDIZER. Store in a cool, well ventilated area away from all sources of ignition and out of direct sunlight. Store in a dry location away from heat. Keep away from incompatible materials. Keep containers tightly closed. Do not store in unlabeled or mislabeled containers. Avoid contact with combustible materials, wood and organic materials.

HANDLING:

Avoid contact with eyes, skin, and clothing. Use with adequate ventilation. Do not swallow. Avoid breathing vapors, mists, or dust. Do not eat, drink, or smoke in work area. Wash thoroughly after handling.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS:

General room ventilation and local exhaust are required. Maintain adequate ventilation. Do not use in closed or confined spaces. Avoid creating dust or mist.

RESPIRATORY PROTECTION:

Respiratory protection may be required to avoid overexposure when handling this product.

Material Safety Data Sheet

SODIUM NITRITE HIGH PURITY GRANULAR

Page 4 of 6

Revised 2005-01-10 11:21:45

Replaces 2002-10-22 13:53:27

As of 2006-07-19 00:27:32

MSDS ID: NAI402

If dust or mist is present, wear: NIOSH-Approved respirator for dusts and mists. NIOSH-Approved self-contained breathing apparatus. DO NOT exceed limits established by the respirator manufacturer. All respiratory protection programs must comply with OSHA 29 CFR 1910.134 and ANSI Z88.2 requirements and must be followed whenever workplace conditions require a respirator's use.

EYE/FACE PROTECTION:

Wear chemical safety goggles while handling this product.
Do not wear contact lenses.

SKIN PROTECTION:

Prevent contact with this product. Wear gloves and protective clothing depending on condition of use.
Protective gloves: Chemical-resistant. Rubber.

OTHER PROTECTIVE EQUIPMENT:

Eye-wash station. Safety shower. Rubber apron. Rubber boots. Protective clothing.

GENERAL HYGIENE CONSIDERATIONS:

Wash with soap and water before meal times and at the end of each work shift.

EXPOSURE GUIDELINES:

COMPONENT	-----OSHA-----	-----ACGIH-----		
	PEL	STEL/C	TWA	STEL/C
Sodium Nitrite	Not Estab.	Not Estab.	Not Estab.	Not Estab.

9. PHYSICAL AND CHEMICAL PROPERTIES

BOILING POINT (DEG. F) : 608	SPECIFIC GRAVITY: 2.17
Decomposes	
FREEZING POINT (DEG. F) : N.D.	% VOLATILE (WT%): N.A.
MELTING POINT (DEG. F) : 520	EVAPORATION RATE: N.A.
VAPOR PRESSURE (MM HG) : N.A.	(nBuAc=1)
VAPOR DENSITY (AIR=1) : N.A.	VOC (WT%) : 0
SOLUBILITY IN WATER : 46% @ 68F	VOC (LBS/GAL) : 0
pH : -9 (aqueous solution)	

10. STABILITY AND REACTIVITY

STABILITY:

Stable under normal conditions.

CONDITIONS TO AVOID:

Avoid elevated temperatures. Solutions are oxidized by air.

INCOMPATIBILITY:

Acids. Ammonium compounds. Amines. Reducing agents. Organic materials. Combustible materials. Cyanides. Sulfites. Metabisulfites.

HAZARDOUS DECOMPOSITION PRODUCTS:

At elevated temperatures, product will decompose generating: Nitrogen oxides. Acids can cause the formation of nitrogen oxides.

HAZARDOUS POLYMERIZATION:

Will not occur under normal conditions.

Material Safety Data Sheet

SODIUM NITRITE HIGH PURITY GRANULAR

Page 5 of 6

Revised 2005-01-10 11:21:45

Replaces 2002-10-22 13:53:27

As of 2006-07-19 00:27:32

MSDS ID: NA1402

11. TOXICOLOGICAL INFORMATION

LD50 ORAL : Rat: 180 mg/kg
LD50 SKIN : No Data
LC50 INHALATION: No Data

Multiple reproductive tests indicate that sodium nitrite is not teratogenic. Fetal toxicity has been demonstrated in pregnant animals fed toxic doses of sodium nitrite. This is due to the formation of methemoglobin.

12. ECOLOGICAL INFORMATION

ECOTOXICOLOGICAL INFORMATION:

17.1 ppm/24hr./minnow/no effect/fresh water
7.5 ppm/48 hr./mosquito fish/TLM/fresh water

CHEMICAL FATE INFORMATION:

No data available.

13. DISPOSAL CONSIDERATIONS

HAZARDOUS WASTE NUMBER: D001

DISPOSAL METHOD:

Dispose of in a permitted hazardous waste management facility following all local, state and federal regulations.
Incinerate or bury in a licensed facility. Since emptied containers retain product residue, follow label warnings even after container is emptied. DO NOT pressurize, cut, weld, solder, drill, grind or expose empty containers to heat, flame, sparks or other sources of ignition.

14. TRANSPORT INFORMATION (Not meant to be all inclusive)

DOT (Department of Transportation):

Proper Shipping Name : SODIUM NITRITE
Hazard Class : 5.1 (6.1)
Identification Number : UN1500
Packing Group : PGIII
Label Required : OXIDIZER; TOXIC
Reportable Quantity (RQ): 100# (Sodium Nitrite)

15. REGULATORY INFORMATION

FEDERAL REGULATIONS:

TSCA INVENTORY STATUS:

All components of this product are on the TSCA Inventory or are exempt from TSCA Inventory requirements.
Requires export notification (Section 12b) Subject to SNUR if used in metalworking fluids (40 CFR 721.4740).

SARA TITLE III SECTION 311/312 CATEGORY:

IMMEDIATE (ACUTE) HEALTH HAZARD : YES
DELAYED (CHRONIC) HEALTH HAZARD : YES
FIRE HAZARD : YES
SUDDEN RELEASE OF PRESSURE HAZARD: NO
REACTIVE HAZARD : NO

SARA SECTION 302/304/313/HAP:

COMPONENT	RQ (LBS) (*1)	RQ (LBS) (*2)	TPQ (LBS) (*3)	SEC 313 (*4)	HAP (*5)
Sodium Nitrite	100	N.A.	N.A.	YES	NO

Material Safety Data Sheet

SODIUM NITRITE HIGH PURITY GRANULAR

Page 6 of 6

Revised 2005-01-10 11:21:45

Replaces 2002-10-22 13:53:27

As of 2006-07-19 00:27:32

MSDS ID: NA1402

-----FOOTNOTES-----

*1 = CERCLA Reportable Quantity *3 = SARA EHS Threshold Planning Quantity
*2 = SARA Reportable Quantity *4 = SARA 313 Toxic Chemical Category

STATE REGULATIONS:

CALIFORNIA--The following components are listed under Prop 65:
No data available.

WISCONSIN--The following components are listed as a Wisconsin HAP:
None.

16. OTHER INFORMATION

HMIS RATING SYSTEM

Health : 2*
Flammability: 0
Reactivity : 1

* = Chronic Health Hazard

NFPA RATING SYSTEM

Health : 2
Flammability : 0
Reactivity : 1

Special Hazard: OX

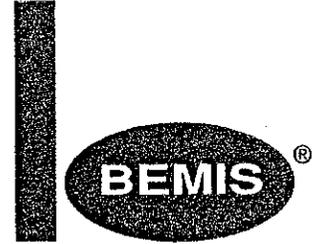
MSDS ABBREVIATIONS: N.A. = Not Applicable
N.D. = Not Determined
HAP = Hazardous Air Pollutant
VOC = Volatile Organic Compound
C = Ceiling Limit
N.E./Not Estab. = Not Established

MSDS PREPARED BY: KJL

REASON FOR REVISION: Product name change.

The data in this Material Safety Data Sheet relates only to the specific material designated and does not relate to its use in combination with any other material or process. The data contained is believed to be correct. However, since conditions of use are outside our control it should not be taken as a warranty or representation for which HYDRITE CHEMICAL CO. assumes legal responsibility. This information is provided solely for your consideration, investigation, and verification.

BEMIS COMPANY, INC.



May, 14, 2007

Ms. Elizabeth Harrison
Attorney at Law
Keller and Heckman
1001 G Street NW
Washington, DC 20001

2200 Badger Avenue
P.O. Box 2968
Oshkosh, WI 54903-2968
(920) 303-7300
FAX: (920) 303-7309

Dear Ms. Harrison,

Confidential

Re: Federal Food, Drug and Cosmetic Act as amended documentation for the Sodium Nitrite Carrier Resins

The potential carrier resins used comply with the appropriate Federal Food, Drug and Cosmetic Act Regulations as amended.

- 1) Ultra Linear Low Density Polyethylene (ULLDPE).
It complies with 21CFR 177.1520 (c) 3.2a
- 2) Ethylene Vinyl Acetate Copolymer – (EVA) – 5% in Low Density Polyethylene (LDPE).
- 3) All resins and additives used by Curwood, Inc. for food packaging applications comply with the appropriate Federal Food, Drug and Cosmetic Act as amended.

We trust this information will be suitable for your needs.

For Curwood, Inc. a Bemis Company
Sincerely,

Don Turner
Director, Product Safety & Stewardship
Bemis Company, Inc.

File

APPENDIX 2

Nitrite/Nitrate Analyses for Ground Beef and Strip Steaks

Loading Level of Sodium Nitrite in Packaging film = 105 mg/m²

Detection Limit of the Analytical Method = 0.7 ppm

Product Type	Time Post-Packaging (days)	Samples Tested (n)	Nitrite Ion Concentration in Sample (ppm)			P Level	Nitrate Ion Concentration in Sample (ppm)			P Level
			Control	Test	Difference		Control	Test	Difference	
Ground Beef	2	10	ND*	ND*	ND*	-	2.21	4.36	2.15	<0.0001
Ground Beef	4	2	ND*	ND*	ND*	-	2.11	3.80	1.69	0.0066
Ground Beef	26	1	ND*	ND*	ND*	-	4.85	7.74	2.89	n/a
Strip Steak	2	5	ND*	ND*	ND*	-	2.27	5.08	2.81	<0.0002
Strip Steak	4	2	ND*	ND*	ND*	-	2.37	6.99	4.62	0.0210
Strip Steak	24	2	ND*	ND*	ND*	-	6.61	7.14	0.53	0.7127
Strip Steak	36	5	0.17	0.46	0.29	0.0622	0.29	0.90	0.61	0.2900
Strip Steak	48	3	0.12	0.07	-0.05	0.7287	0.26	2.80	2.54	0.0104
Average	-	-	-	-	-	-	2.62	4.85	2.23	-

* ND ≡ Not Detected

Page has been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

Memorandum

TO: Matt Mengel, Dave Busche, Otacilio Berbert, Kevin Nelson, Chris Nimis

CC: Dan Siegel

FROM: Ryan Michaud—Product Development Engineer, Curwood

DATE: May 14, 2007

RE: Post-Opening Color Study on Beef

Summary:

The experiment was designed to assess and compare (a) the color of unwrapped raw beef that was previously vacuum packaged in sodium nitrite-containing packaging film, to (b) the color of unwrapped raw beef that was previously vacuum packaged in plain packaging film.

Materials and Methods:

Color data for this experiment was logged using the CIE $L^*a^*b^*$ (CIELAB) color model. This system is used conventionally to describe all the colors visible to the human eye and was developed for this specific purpose.

The three parameters in the model combine to represent the lightness of the sample color (L^* , $L^*=0$ indicates black and $L^*=100$ indicates white), its position between magenta and green (a^* , negative values indicate green and positive values indicate magenta), and its position between yellow and blue (b^* , negative values indicate blue and positive values indicate yellow). For the measurement of raw beef color, the “ a^* ” value is most relevant because it indicates redness, with higher “ a^* ” values representing a redder color than lower “ a^* ” values. A three dimensional representation of the CIELAB color model appears below in Figure 1.

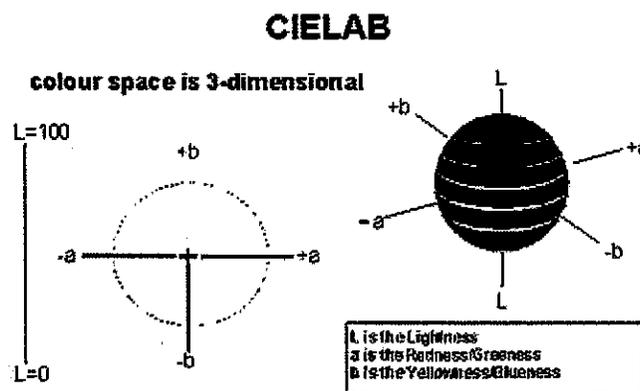


Figure 1: CIELAB Color Model

Source: <http://www.colourware.co.uk/cpfaq/q3-21.htm> 14 May 2007



A Konica-Minolta Baking Meter BC-10 was used to determine the L*, a*, and b* values for each sample over time. A white plate is included with the BC-10, which is used to calibrate the baking meter each time it is turned on. Each BC-10 has its own specific plate to be calibrated with and both are marked with the corresponding serial number. Both the BC-10 and calibration plate used in this experiment are marked with the serial #09575. Specifications for the BC-10 are given below in Table I.

Table I: Konica-Minolta BC-10 Specifications

Specification	BC-10
Illumination/Viewing Geometry	8/d (8° illumination angle/diffuse viewing)
Measurement Diameter	~ 8 mm
Light Source	Gas-filled Tungsten Lamp
Detector	6 Silicon Photocells
Calibration Accessory	White Calibration Plate CR-A43

Raw beef shoulder roasts were vacuum packaged in (a) high barrier forming and non-forming films with sodium nitrite in the sealant layer of the non-forming film for the test samples, and (b) high barrier forming and non-forming films for an experimental control. All samples were packaged on March 27, 2007. The beef's color was monitored over time, with measurements taken by viewing the side of the beef in contact with the non-forming film. Color was assessed while the beef was in the vacuum packaged high barrier film and also in the post-packaging environment (i.e., after being unwrapped), when the beef was wrapped in an air-permeable, breathable polyvinyl chloride (PVC) film to protect the beef from moisture loss when exposed to a refrigerated atmosphere. Both the test and control samples were marked with crosshairs to ensure the same location on the non-forming film side of the meat surface was measured each time. Five measurements were taken and averaged to determine the color scores for each sample. Samples were stored under light in a refrigerated environment at approximately 3°C and 40% relative humidity.

The non-forming film containing sodium nitrite used to packaged the test samples was produced under Curwood project X239-0125-B, and was loaded with 105 mg/m² of sodium nitrite. The control samples were packaging in non-forming film that was produced under Curwood project X239-0127-B, that was a 5 mil version of specification 9506. The thickness of the non-forming film was 5 mils for both the control and test films.

Results:

On April 5, 2007 an initial color reading was taken on the raw beef shoulder roasts while in their original high-barrier packaging. The samples were then removed from the vacuum packaging and wrapped in breathable PVC film to monitor color over time. Definitions of project variables can be found in Table II below.

Table II: Project Variable Definitions

Project Performance Metric		
ABBREVIATION	FILM IDENTIFICATION	DEFINITION
S#		SAMPLING NUMBER
C1	Non-Forming: X239-0127-B 5 MIL	CONTROL - Beef roast initially packed in high barrier non-forming film with no sodium nitrite
T1	Non-Forming: X239-0125-B 5 MIL (105 mg/m ² NaNO ₂)	TEST - Beef roast initially packed in high barrier non-forming film with sodium nitrite
L		Represents the lightness of the color (L, L=0 yields black and L=100 indicates white)
a		Represents its position between magenta and green (a, negative values indicate green while positive values indicate magenta)
b		Represents its position between yellow and blue (b, negative values indicate blue and positive values indicate yellow).
% Change	$\% \text{ Change} = \frac{(\text{Actual Value} - \text{Time Zero Value})}{(\text{Time Zero Value})} \times 100\%$	Indicates the percent change between the actual reading and the initial reading at time zero.

The last color reading of the beef while it was still in high-barrier packaging (considered time zero for this study) indicated the test beef roast variable had a higher "a*" value, or was redder than the control roast. The color scores for the control roast were L = 44.0, a = +10.2, b = +6.2, while the test roast had scores of L* = 32.2, a* = +16.9, b* = +6.4. The higher "a*" value of the test roast over the control roast was expected. At each color measurement after the roasts were removed from the high barrier film, from the first measurement at 10 minutes post-opening to the last measurement at 21 hours 15 minutes post-opening, the control roast exhibited a higher "a*" value score. The data is presented below in Table III and Figures 2 through 4.

Table III: Measured Color Values

S#	Time Stamp	Time from Start (hours)	L		a		b		Comments
			Actual	% Change	Actual	% Change	Actual	% Change	
C									
C1.1	4/5/2007 10:15	0:00:00	44.0	-	10.2	-	6.2	-	High Barrier Vacuum Packaging
C1.2	4/5/2007 10:25	0:10:00	41.8	-5.0%	18.4	80.4%	11.3	82.3%	Breathable PVC Wrap
C1.3	4/5/2007 11:00	0:45:00	41.8	-5.0%	20.2	98.0%	12.0	93.5%	Breathable PVC Wrap
C1.4	4/5/2007 12:00	1:45:00	44.3	0.7%	21.2	107.8%	12.7	104.8%	Breathable PVC Wrap
C1.5	4/5/2007 13:00	2:45:00	44.8	1.8%	21.9	114.7%	13.3	114.5%	Breathable PVC Wrap
C1.6	4/5/2007 14:00	3:45:00	45.2	2.7%	22.5	120.6%	13.5	117.7%	Breathable PVC Wrap
C1.7	4/5/2007 15:00	4:45:00	45.2	2.7%	22.2	117.6%	13.2	112.9%	Breathable PVC Wrap
C1.8	4/5/2007 16:00	5:45:00	44.1	0.2%	22.6	121.6%	13.5	117.7%	Breathable PVC Wrap
C1.9	4/5/2007 17:00	6:45:00	43.6	-0.9%	23.4	129.4%	13.2	112.9%	Breathable PVC Wrap
C1.10	4/5/2007 18:00	7:45:00	45.2	2.7%	22.7	122.5%	13.5	117.7%	Breathable PVC Wrap
C1.11	4/6/2007 7:30	21:15:00	43.5	-1.1%	22.4	119.6%	12.7	104.8%	Breathable PVC Wrap
T									
T1.1	4/5/2007 10:15	0:00:00	32.2	-	16.9	-	6.4	-	High Barrier Vacuum Packaging
T1.2	4/5/2007 10:25	0:10:00	34.9	8.4%	17.9	5.9%	7.4	15.6%	Breathable PVC Wrap
T1.3	4/5/2007 11:00	0:45:00	35.1	9.0%	20.0	18.3%	8.5	32.8%	Breathable PVC Wrap
T1.4	4/5/2007 12:00	1:45:00	35.3	9.6%	19.5	15.4%	8.4	31.3%	Breathable PVC Wrap
T1.5	4/5/2007 13:00	2:45:00	34.7	7.8%	19.7	16.6%	8.2	28.1%	Breathable PVC Wrap
T1.6	4/5/2007 14:00	3:45:00	34.9	8.4%	20.1	18.9%	8.5	32.8%	Breathable PVC Wrap
T1.7	4/5/2007 15:00	4:45:00	35.5	10.2%	18.7	10.7%	8.3	29.7%	Breathable PVC Wrap
T1.8	4/5/2007 16:00	5:45:00	35.5	10.2%	17.5	3.6%	8.1	26.6%	Breathable PVC Wrap
T1.9	4/5/2007 17:00	6:45:00	37.1	15.2%	14.6	-13.6%	6.2	-3.1%	Breathable PVC Wrap
T1.10	4/5/2007 18:00	7:45:00	34.9	8.4%	17.0	0.6%	7.9	23.4%	Breathable PVC Wrap
T1.11	4/6/2007 7:30	21:15:00	34.1	5.9%	14.5	-14.2%	6.8	6.2%	Breathable PVC Wrap

Raw Beef Color Study

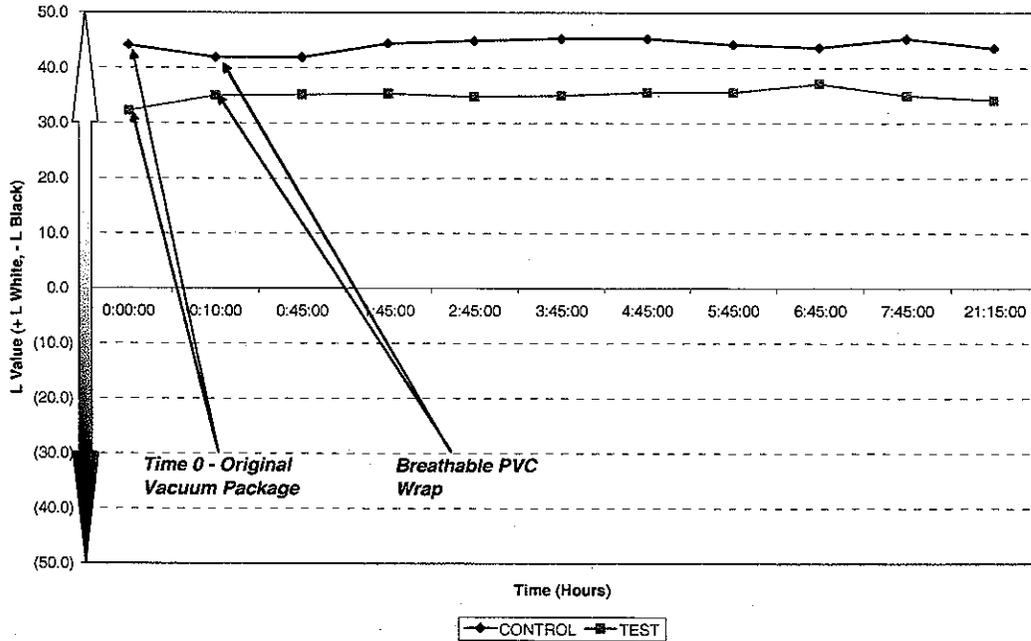


Figure 2: "L*" Values Over Time

Raw Beef Color Study

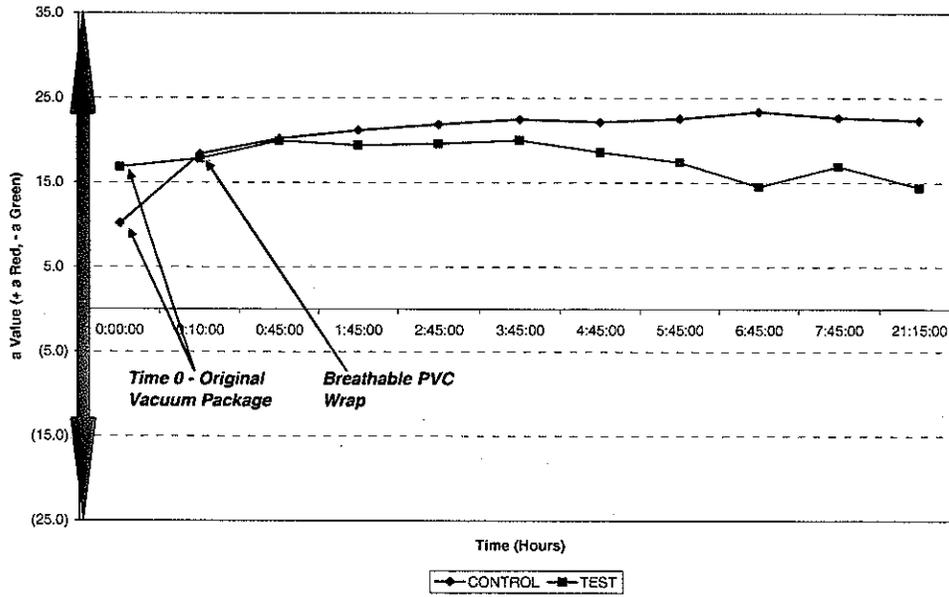


Figure 3: "a*" Values Over Time

Raw Beef Color Study

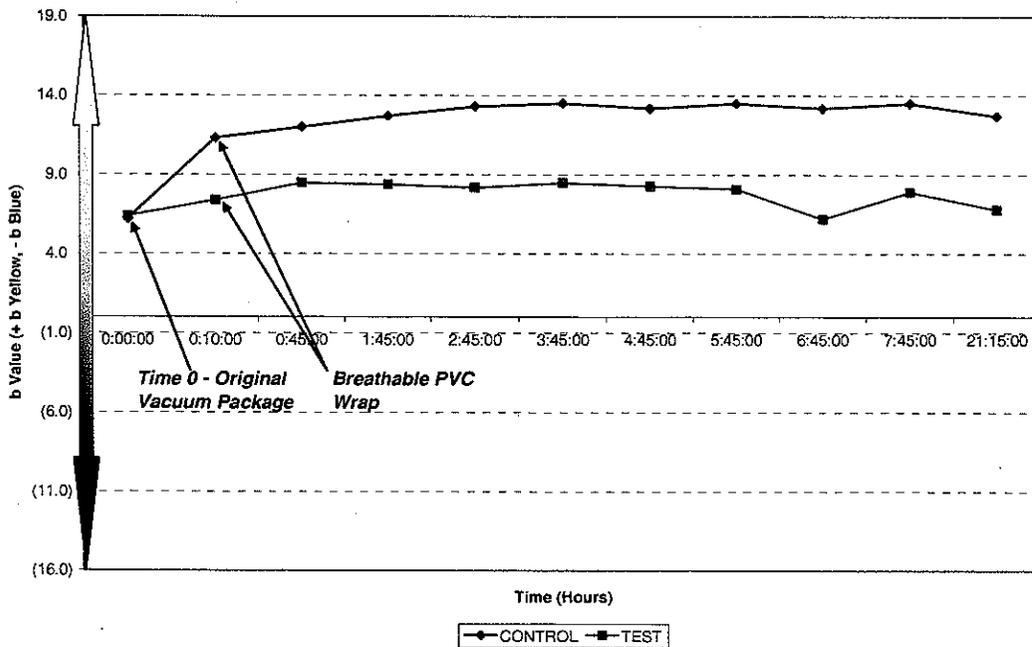
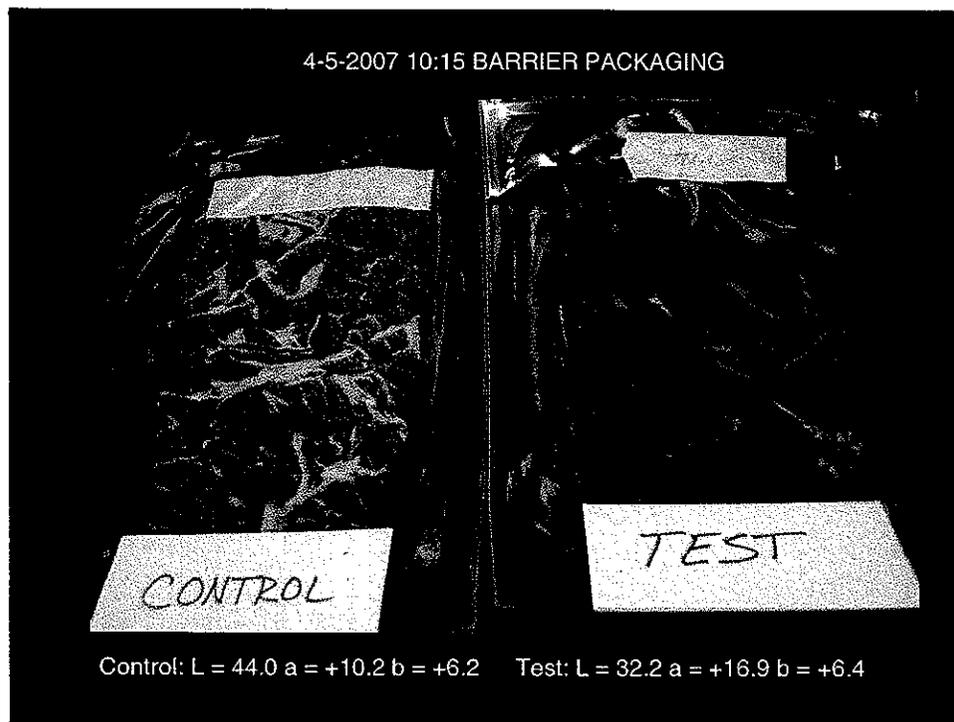
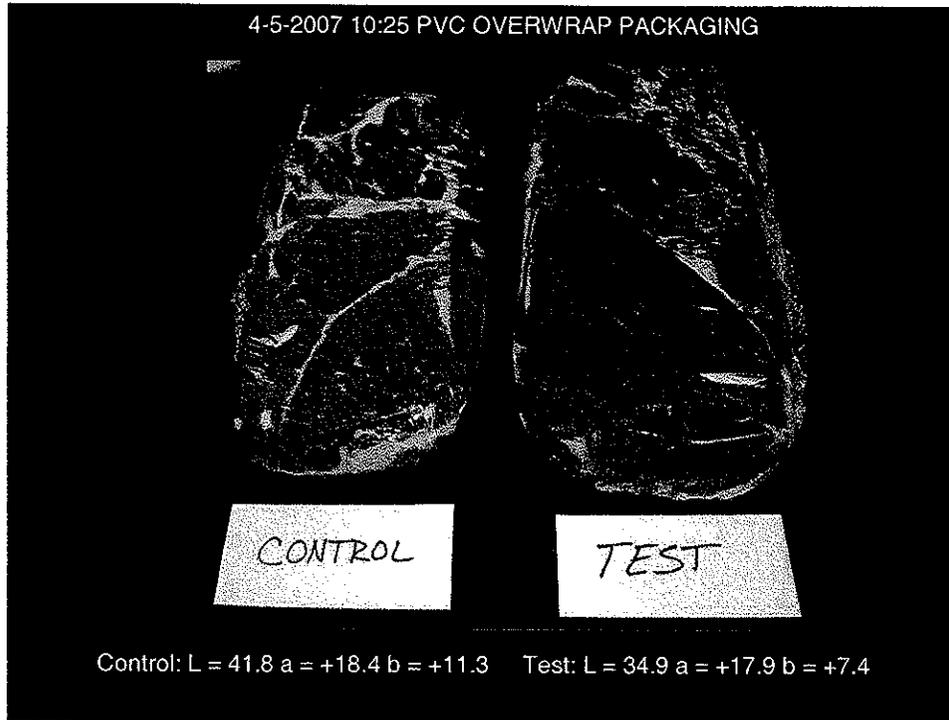


Figure 4: "b*" Values Over Time

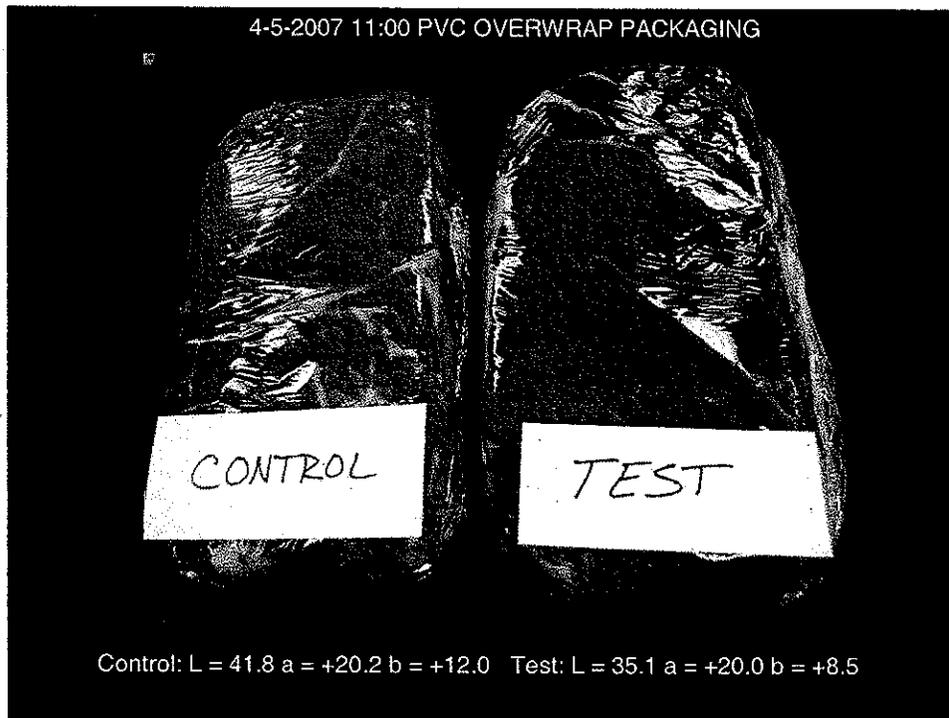
Conclusion:

The study found that, while the raw beef roasts were still in the vacuum packaging, the beef packaged in Bemis's sodium nitrite-containing film was a brighter red color than raw beef roasts packaged in plain film. After the packages were opened, however, the opposite color differentiation was observed. Specifically, the beef packaged in plain film exhibited a brighter red color than the beef packaged in Bemis's sodium nitrite-containing film, and this color differentiation was visible at each measurement, from 10 minutes post-opening to 21 hours and 15 minutes post-opening.

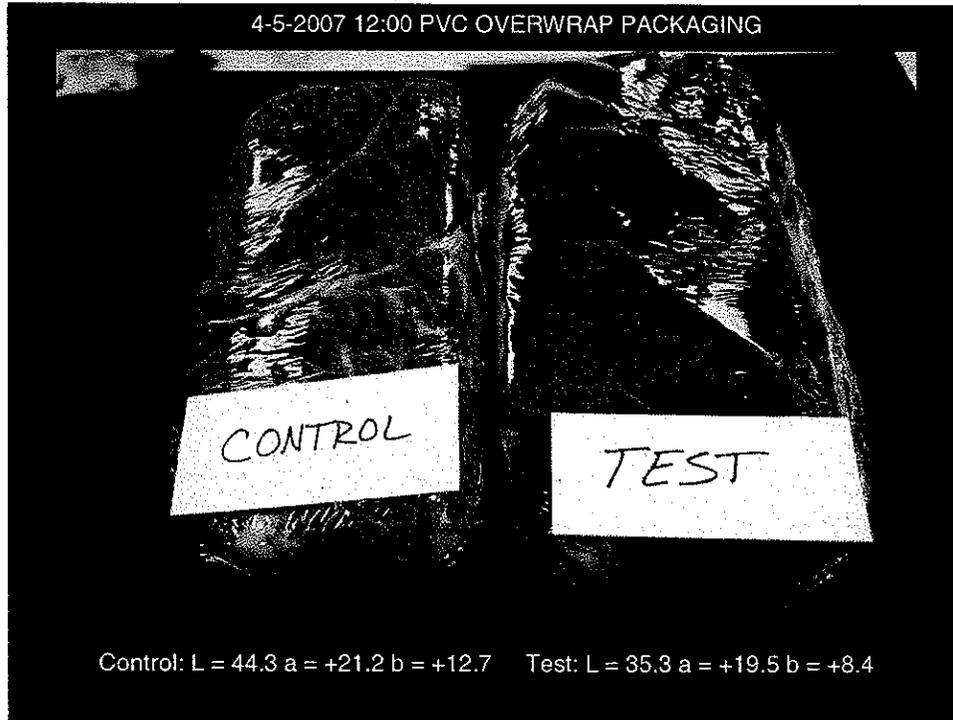
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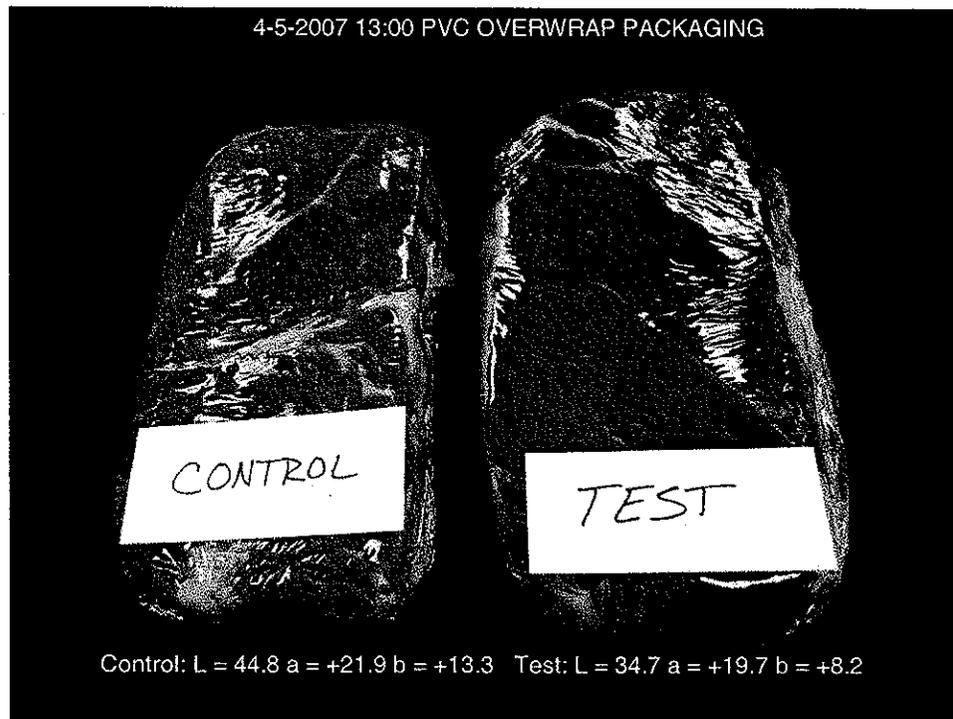
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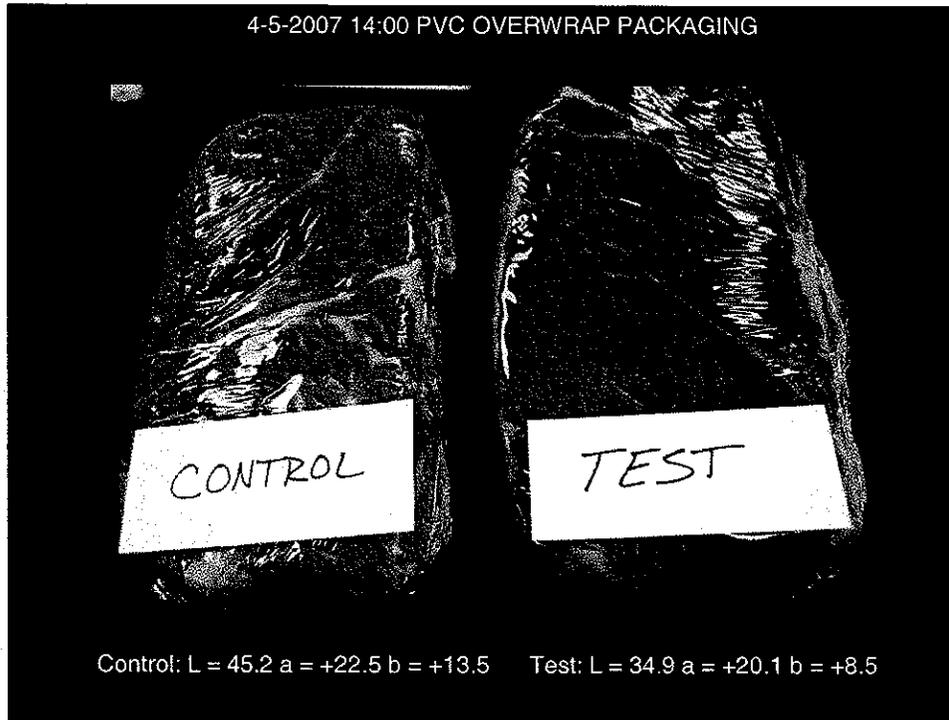
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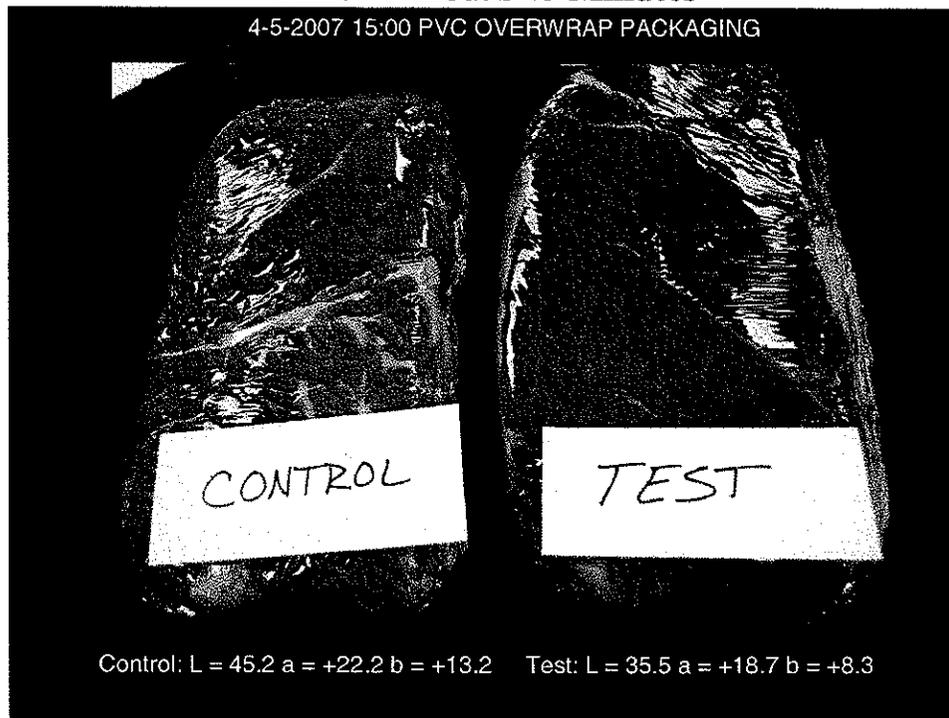
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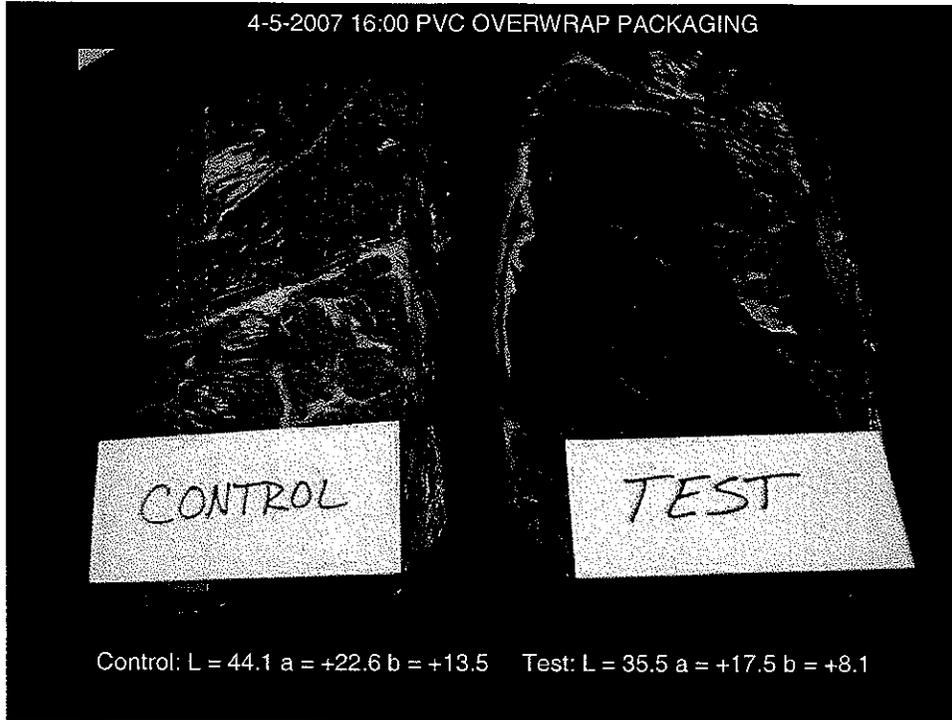
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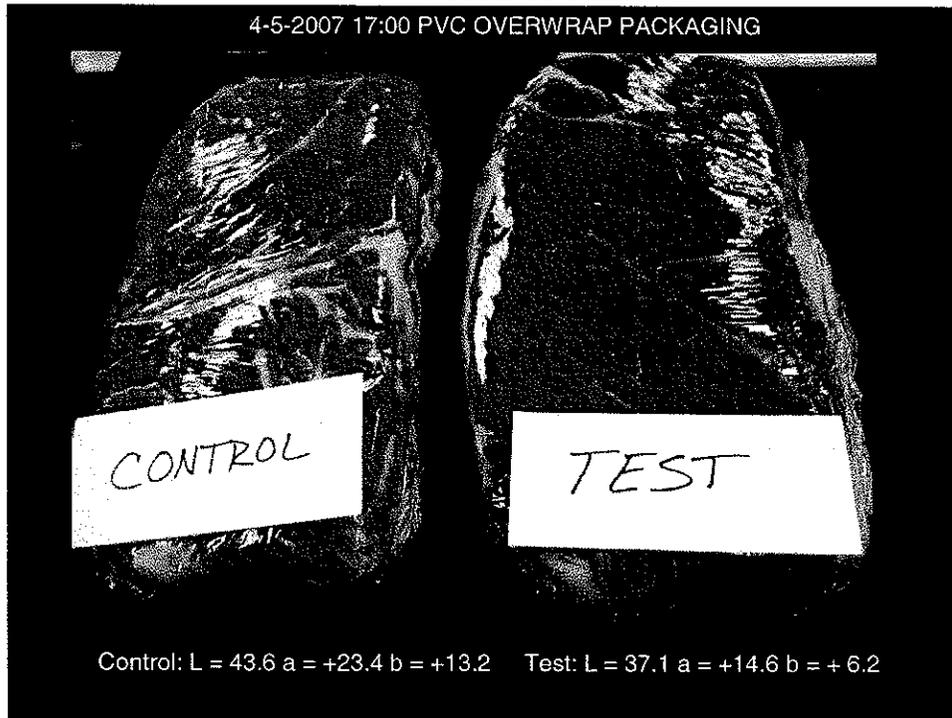
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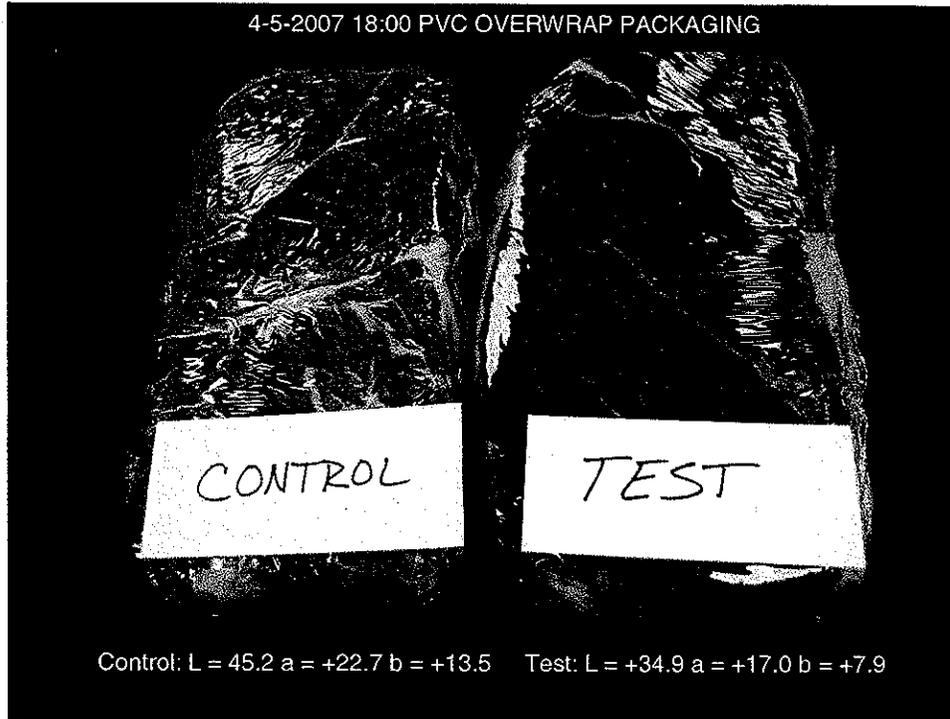
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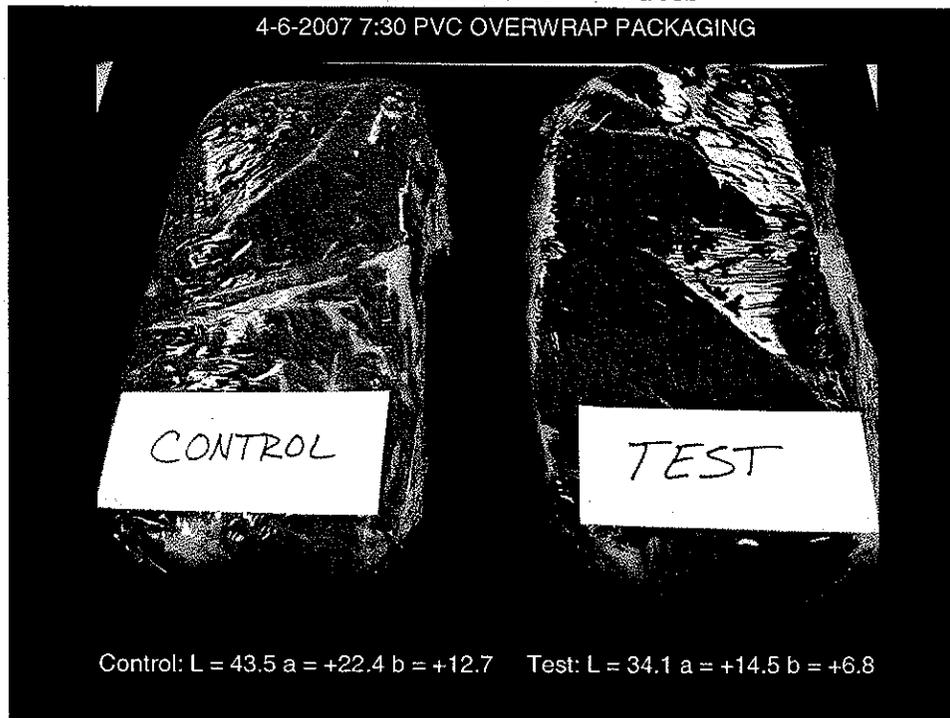
Time: 5 Hours 45 Minutes



Time: 6 Hours 45 Minutes



Time: 7 Hours 45 Minutes



Time: 21 Hours 15 Minutes

GR



SUBMISSION END

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