

GR



GRAS Notice (GRN) No. 167

<http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/default.htm>

ORIGINAL SUBMISSION

000001

RECEIVED AT OFAS APRIL 4, 2005

OLSSON, FRANK AND WEEDA, P.C.

PHILIP C. OLSSON
RICHARD L. FRANK
DAVID F. WEEDA (1948-2001)
DENNIS R. JOHNSON
ARTHUR Y. TSIEN
JOHN W. BODE*
STEPHEN D. TERMAN
MARSHALL L. MATZ
MICHAEL J. O'FLAHERTY
DAVID L. DURKIN
NEIL F. O'FLAHERTY
PAMELA J. FURMAN
BRETT T. SCHWEMER
TISH E. PAHL
ROBERT A. HAHN

ATTORNEYS AT LAW
SUITE 400
1400 SIXTEENTH STREET, N.W.
WASHINGTON, D. C. 20036-2220
(202) 789-1212
FACSIMILE (202) 234-3550

Sender's Direct Phone (202) 518-6327
Sender's Direct Facsimile (202) 234-2686

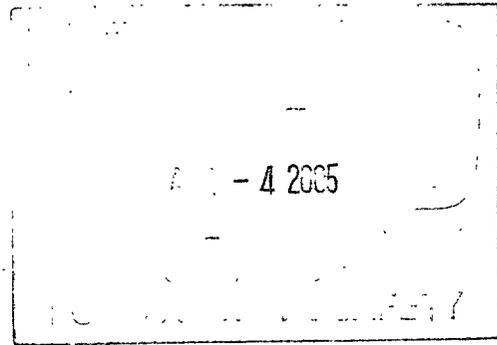
STEPHEN L. LACEY
EVAN P. PHELPS
VALERIE B. SOLOMON
JOLYDA O. SWAIM
KATHRYN E. BALMFORD
COUNSEL
NAOMI J. L. HALPERN
OF COUNSEL
JUR. T. STROBOS
JACQUELINE H. EAGLE
KENNETH D. ACKERMAN
MARK L. ITZKOFF
DAVID A. BIEGING
SR. GOVERNMENT AFFAIRS ADVISOR
JOHN R. BLOCK
CHARLES W. STENHOLM
BRIAN E. JOHNSON
SALLY S. DONNER

*PRACTICE WITHIN THE DISTRICT OF COLUMBIA
IS LIMITED TO MATTERS AND PROCEEDINGS
BEFORE FEDERAL COURTS AND AGENCIES

April 1, 2005

BY FEDERAL EXPRESS

Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food And Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835



Dear Sirs:

On behalf of our client, Tyson Foods, Inc., we are hereby submitting the enclosed Generally Recognized As Safe (GRAS) Notification for the use of carbon monoxide (CO) in modified atmosphere packaging (MAP) for red meat products. As discussed in this Notice, the application discussed herein is essentially the same as the application previously reviewed by FDA under GRASN 143. This notification does not represent any increase in dietary exposure to CO.

In GRASN 143, FDA considered the use of CO in MAP packaging where the concentration of CO in the gas did not exceed 0.4 percent by volume. While not explicitly stated in FDA's response, the exposure estimates were based upon a 1:1 volume ratio of MAP gas to the packaged meats. In this notice, Tyson Foods is notifying the agency of its determination that the use of CO at higher concentrations is also deemed to be GRAS provided that the volume of packaging gas is reduced proportionately, and that the final quantity of CO does not increase.

Should you have any questions regarding this notice, please do not hesitate to contact us.

Sincerely,

BEST ORIGINAL COPY

Mark L. Itzkoff

MLI:jdm
Enclosures

000002

**GRAS Claim for the Use of Carbon Monoxide
In Modified Atmosphere Packaging
For Red Meat Products**

Submitted by Tyson Foods, Inc.

April 1, 2005

000003

Section I

GRAS Claim

Tyson Foods, Inc. hereby submits this GRAS claim for the use of carbon monoxide (CO) in modified atmosphere packaging (MAP) for red meat products.

A. Name and Address of Notifier:

Tyson Foods, Inc.
2210 Oaklawn Drive
Springdale, Arkansas 72765

B. Common or Usual Name of Substance:

The common or usual name of the substance is carbon monoxide. The Chemical Abstract Services Registration Number (CASRN) for this substance is 630-08-0.

C. Conditions of Use:

In this Notification, CO will be used in Modified Atmosphere Packaging (MAP) packaging for red meat products where the quantity of CO in the MAP gases does not exceed 2.2 mg per pound of packaged meat. This application is the same end use and technical purpose, MAP packaged red meat products, described in GRAS Notices GRASN 83 and 143. This Notice differs only in the concentration of CO in the MAP gas and the quantity of MAP gas in the packaging. As shown in this application, the permissible quantity of CO per pound of beef proposed herein is the same quantity proposed in GRASN 143. Therefore, this notice does not propose any increase in the dietary exposure to carbon monoxide.

In the previous notices, CO was added to the gas mixture used to package red meat. The CO was added to the MAP gases at a concentration not to exceed 0.4% by volume. While the notices did not include limits on the volume of gas per pound of meat, our calculations show that the limit is based on equal volumes of meat and MAP gas.¹ In this application, the volume of MAP gas will decrease allowing for an increase in the concentration of CO in the gas without any increase in the total quantity of CO in the package. Rather than limit the concentration of CO in the gas, we are proposing that FDA limit the quantity of CO so that the potential exposure does not exceed the exposure that would occur under the two previous Notices, 1.2 mg per 8.8 ounce serving of beef (2.2 mg/lb).²

¹ See Table 1 in Appendix I.

² See Agency Response Letter, GRAS Notice No. GRN 000143 (July 29, 2004), <http://www.cfsan.fda.gov/~rdb/opa-g143.html>.

000004

D. Basis for GRAS Determination:

FDA has previously reviewed the safety of the use of CO in modified atmosphere packaging in two GRAS Notifications, GRASN 83 and 143. The data submitted to FDA in those Notices is hereby included by reference in this Notice.

The use of CO proposed herein will not result in any increased dietary exposure to CO. The dietary exposure will not increase because the potential concentration of CO in red meat packaged using the method described herein will be less than or equal to the levels that are expected to result from the applications detailed in the previous Notices. Since the product packaged using the modified atmosphere gases detailed in this Notice is the same product currently packaged using the gases detailed in the previous Notices, the exposure to CO from this proposed use is already included in the exposure estimates for the previous Notices, *i.e.*, there will be no increase in CO consumption. Since neither the concentration of CO in the processed food nor new applications for CO will result from the use described herein, there will be no increase in total dietary exposure. Therefore, the data used to support the two effective GRAS Notices also demonstrate the safety of CO in this application.

In addition, since the method of exposure to CO, packaging with CO-containing MAP gases, is the same exposure method reviewed previously, the studies previously cited to demonstrate that the use of CO in application will not "mask" normal spoilage of the processed red meat during storage prior to use by consumers also demonstrate that the Tyson Food's method will not mask normal spoilage.

E. Data Availability Statement:

The data and information that are the basis for the Notifier's GRAS determination will be sent to FDA upon request.

Respectfully Submitted,

Mark L. Itzkoff
Counsel for Tyson Foods, Inc.

000005

Section II

Identity of the Notified Substance

The substance that is the subject of this Notice is Carbon Monoxide (CO), a colorless, odorless gas, with the CASRN 630-08-0. A Material Safety Data Sheet for this material is attached in Appendix II.

The specific CO used in this process will be commercial, "food grade" CO. The purity specifications will be the same as those set forth for CO in GRASN 143, *i.e.*, the minimum purity will be 98 percent carbon monoxide while the other 2 percent will be residual atmospheric gases (nitrogen, oxygen, carbon dioxide, argon, water, hydrogen and/or methane). Thus, the use of carbon monoxide set forth herein will not result in the introduction into processed red meat of any materials not previously considered under GRASN's 83 and 143.

000006

Section III

Information on Self-Limiting Levels of Use

FDA has previously reviewed the use of carbon monoxide in modified atmosphere packaging where up to 0.4% of CO would be present in the MAP gas and the gas would be used in a package where the volume of the package was twice the volume of the packaged meat, *i.e.*, the volume of the MAP gas is equal to the volume of the packaged meat.³ As noted in the Agency Response Letter to GRAS Notice No. GRN 000143, Precept, the Notifier in GRN143 estimated that "if 100 percent of the CO in the package is absorbed, and 100 percent of the CO is consumed, an 8.8 ounce serving would expose the consumer to 1.2 mg of CO." Tyson Foods, Inc. is proposing to use CO in other packaging configurations where the concentration of CO in the gas will exceed 0.4% but the ratio of CO to packaged beef will remain the same as in GRASN 143, 2.2 mg per pound.

For example, in one package configuration one pound of beef (454 g) will be packaged in a container with a volume of 620 ml. Assuming the beef has a density of 1.0 g/ml, 1 lb of beef will occupy 454 ml of volume, leaving 166 ml of "headspace" for the MAP gas.

$$(620 \text{ ml package volume}) - (454 \text{ ml beef volume}) = 166 \text{ ml headspace}$$

If the concentration of CO in the gas is 1.0 percent by volume, the volume of CO in the package will be 1.66 ml. The density of CO is 1.25 mg/ml, so 1.66 ml of CO is

$$(1.66 \text{ ml})(1.25 \text{ mg/ml}) = 2.1 \text{ mg.}$$

Thus, the ratio of CO to beef will be 2.1 mg per pound, essentially the same as the ratio in GRASN 143 and is small when compared to the level of CO exposure deemed to be safe by the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA)⁴

³ See Table 1.

⁴ "EPA's National Ambient Air Quality Standards is 9 ppm CO in air, resulting in the inhalation of 52 mg CO in 8 hours. The OSHA Permissible Exposure Limit is 50 ppm in air, resulting in the inhalation of 290 mg CO in 8 hours." FDA, Agency Response Letter GRAS Notice No. GRN 000143, July 29, 2004 (footnote 1).

Tyson Foods, Inc.
GRAS Notification for Carbon Monoxide
April 1, 2005

In the previous GRASN's, both Precept Foods and Pactiv Corporation estimated that 85% of the CO present in the uncooked red meat would volatilize out of the meat during cooking. Using the same estimate, the quantity of CO present in 8.8 ounces of cooked red meat would be:

$$(1.2 \text{ mg})(0.15) = 0.18 \text{ mg}$$

000008

Section IV

Basis for Notifier's Claim

The proposed use of carbon monoxide raises two safety issues: (1) an assessment of the safety of the consumption of CO from the application; and (2) whether the use of CO will "mask" the effect of spoilage organisms on the processed red meat.

The use of CO in the same food products (red meat) is the subject of GRAS Notification 143. The use of CO in this application for beef products was also the subject of GRASN 83. The information referenced in those Notices is hereby included in this Notice by reference. Further, as discussed in Section III, we have demonstrated that the packaging configurations proposed by Tyson Foods, Inc. will not result in any increase in the dietary consumption of carbon monoxide. Since neither the food products nor the potential concentration of CO in those food products will change, the data cited in support of the previous Notifications also demonstrates the safety of carbon monoxide in these packaging applications.

In terms of possible masking of spoilage organisms, the two previous GRAS notices also addressed this issue and found that the use of CO in modified atmosphere packaging did not mask spoilage organisms. The studies discussed in those notices and included by reference in this notice showed that the effect of the CO on the meat, an improvement in the initial meat color, will dissipate before there is significant growth of the spoilage organisms.

In one study conducted by Excel Corporation and submitted to FDA as part of GRASN 143, 3 MAP systems were studied including two containing carbon monoxide and a "control" system containing carbon dioxide and nitrogen. The samples were stored for 5 days at 35°F followed by storage at 50° F. All samples showed similar rates of microbial growth, odor formation and discoloration. Thus the use of CO did not "mask" possible degradation of the packaged beef.

In a study conducted by Hormel and submitted to the agency in GRASN 143, boneless beef strip steaks and top round steaks were packaged in MAP packages and control conditions and stored to simulate retail sale and home storage. Both the CO and control samples were shown to maintain acceptable taste, odor and bacterial levels after 42 days.

Based on the publicly available information previously cited to FDA, Tyson Foods, Inc. has determined that carbon monoxide is generally recognized as safe when used modified atmosphere packaging where the quantity of CO in the MAP gases does not exceed 2.2 mg per pound of packaged meat.

TABLE 1

Volume Calculation for GRASN 143 Exposure

According to GRASN 143, "if 100 percent of the CO in the package is absorbed, and 100 percent of the CO is consumed, an 8.8 ounce serving would expose the consumer to 1.2 mg of CO." Since the Agency response does not specify the dimensions of the package, we will use this information to calculate the volume of MAP gas to beef ratio.

Using the standard gas volume as 1 mole = 22.4 liter (l) at STP, and since 1 mole of CO is 28 grams (g), we calculate the density of CO gas as:

$$(28 \text{ g})/(22.4 \text{ l}) = 1.25 \text{ g/l} = 1.25 \text{ mg/ml}$$

If the package contains 1.2 mg CO per 8.8 ounce serving, then a one kg package will contain:

$$(1.25 \text{ mg}/8.8 \text{ oz})(16 \text{ oz}/\text{lb})(2.2 \text{ lb}/\text{kg}) = 5.12 \text{ mg}/\text{kg}.$$

Further, the volume of CO gas will be:

$$(5.12 \text{ mg}/\text{kg})/(1.25 \text{ mg}/\text{ml}) = 4.1 \text{ ml}/\text{kg beef}$$

Since the CO will be only 0.4% of the MAP gas, the total quantity of gas will be:

$$(4.1 \text{ ml})/(0.004) = 1000 \text{ ml}.$$

Thus the ratio of MAP gas to packaged beef in GRASN 143 was:

$$(1000 \text{ ml MAP gas})/(1000 \text{ g beef}) = 1 \text{ ml MAP gas}/\text{g beef}$$

And, since the density of beef is approximately 1 g/ml,

$$1 \text{ ml MAP gas}/\text{g beef} = \underline{\underline{1 \text{ ml MAP}/\text{ml beef}}}.$$

Table 1

Volume Calculation for GRASN 143 Exposure

According to GRASN 143, "if 100 percent of the CO in the package is absorbed, and 100 percent of the CO is consumed, an 8.8 ounce serving would expose the consumer to 1.2 mg of CO." Since the Agency response does not specify the dimensions of the package, we will use this information to calculate the volume of MAP gas to beef ratio.

Using the standard gas volume as 1 mole = 22.4 liter (l) at STP, and since 1 mole of CO is 28 grams (g), we calculate the density of CO gas as:

$$(28 \text{ g})/(22.4 \text{ l}) = 1.25 \text{ g/l} = 1.25 \text{ mg/ml}$$

If the package contains 1.2 mg CO per 8.8 ounce serving, then a one kg package will contain:

$$(1.25 \text{ mg}/8.8 \text{ oz})(16 \text{ oz}/\text{lb})(2.2 \text{ lb}/\text{kg}) = 5.12 \text{ mg}/\text{kg}.$$

Further, the volume of CO gas will be:

$$(5.12 \text{ mg}/\text{kg})/(1.25 \text{ mg}/\text{ml}) = 4.1 \text{ ml}/\text{kg beef}$$

Since the CO will be only 0.4% of the MAP gas, the total quantity of gas will be:

$$(4.1 \text{ ml})/(0.004) = 1000 \text{ ml}.$$

Thus the ratio of MAP gas to packaged beef in GRASN 143 was:

$$(1000 \text{ ml MAP gas})/(1000 \text{ g beef}) = 1 \text{ ml MAP gas}/\text{g beef}$$

And, since the density of beef is approximately 1 g/ml,

$$1 \text{ ml MAP gas}/\text{g beef} = \underline{\underline{1 \text{ ml MAP}/\text{ml beef}}}.$$

000011

BOC GASES

MATERIAL SAFETY DATA SHEET

PRODUCT NAME: CARBON MONOXIDE

1. Chemical Product and Company Identification

BOC Gases,
Division of
The BOC Group, Inc.
575 Mountain Avenue
Murray Hill, NJ 07974

BOC Gases
Division of
BOC Canada Limited
5975 Falbourne Street, Unit 2
Mississauga, Ontario L5R 3W6

TELEPHONE NUMBER: (908) 464-8100
24-HOUR EMERGENCY TELEPHONE NUMBER:
CHEMTREC (800) 424-9300

TELEPHONE NUMBER: (905) 501-1700
24-HOUR EMERGENCY TELEPHONE NUMBER:
(905) 501-0802
EMERGENCY RESPONSE PLAN NO: 20101

PRODUCT NAME: CARBON MONOXIDE
CHEMICAL NAME: Carbon Monoxide
COMMON NAMES/SYNONYMS: Carbonic Oxide, Exhaust Gas, Flue Gas
TDG (Canada) CLASSIFICATION: 2.3 (2.1)
WHMIS CLASSIFICATION: A, D1A, D2A, D2B, B1

PREPARED BY: Loss Control (908)464-8100/(905)501-1700
PREPARATION DATE: 6/1/95
REVIEW DATES: 6/7/96

2. Composition, Information on Ingredients

INGREDIENT	% VOLUME	PEL-OSHA ¹	TLV-ACGIH ²	LD ₅₀ or LC ₅₀ Route/Species
Carbon Monoxide FORMULA: CO CAS: 630-08-0 RTECS #: FG3500000	100.0	50 ppm TWA	25 ppm TWA	LC ₅₀ 1807 ppm/4H (rat)

¹ As stated in 29 CFR 1910, Subpart Z (revised July 1, 1993)

² As stated in the ACGIH 1994-95 Threshold Limit Values for Chemical Substances and Physical Agents

3. Hazards Identification

EMERGENCY OVERVIEW

Inhaled Carbon Monoxide binds to the blood hemoglobin, greatly reducing the red blood cell's ability to transport oxygen to body tissues. Effects may include headaches, dizziness, convulsions, loss of consciousness and death. Extremely flammable gas.

BEST ORIGINAL COPY

PRODUCT NAME: CARBON MONOXIDE

ROUTE OF ENTRY:

Skin Contact No	Skin Absorption No	Eye Contact No	Inhalation Yes	Ingestion No
--------------------	-----------------------	-------------------	-------------------	-----------------

HEALTH EFFECTS:

Exposure Limits Yes	Irritant No	Sensitization No
Teratogen Yes	Reproductive Hazard Yes	Mutagen Yes
Synergistic Effects None Reported		

Carcinogenicity: -- NTP: No IARC: No OSHA: No

EYE EFFECTS:

None reported.

SKIN EFFECTS:

None reported.

INGESTION EFFECTS:

None reported.

INHALATION EFFECTS:

Inhaled carbon monoxide binds with blood hemoglobin to form carboxyhemoglobin. Carboxyhemoglobin can not take part in normal oxygen transport, greatly reducing the blood's ability to transport oxygen. Depending on levels and duration of exposure, symptoms may include headache, dizziness, heart palpitations, weakness, confusion, nausea, and even convulsions, eventual unconsciousness and death.

Some experimental evidence indicating teratogenic and reproductive effects.

NFPA HAZARD CODES

Health: 2
Flammability: 4
Reactivity: 0

HMIS HAZARD CODES

Health: 2
Flammability: 4
Reactivity: 0

RATINGS SYSTEM

0 = No Hazard
1 = Slight Hazard
2 = Moderate Hazard
3 = Serious Hazard
4 = Severe Hazard

4. First Aid Measures

EYES:

None required.

SKIN EFFECTS:

None required.

INGESTION:

None required.

BEST ORIGINAL COPY

000013

PRODUCT NAME: CARBON MONOXIDE

INGESTION EFFECTS:
None required.

INHALATION:
Conscious persons should be assisted to an uncontaminated area and be treated with supplemental oxygen. Quick removal from the contaminated area is most important. Unconscious persons should be moved to an uncontaminated area and be given artificial respiration and oxygen at the same time. The administering of the oxygen at an elevated pressure (up to 2 to 2.5 atmospheres) has shown to be beneficial as has treatment in a hyperbaric chamber. The physician should be informed that the patient has inhaled toxic quantities of carbon monoxide. **PROMPT MEDICAL ATTENTION IS MANDATORY IN ALL CASES OF OVEREXPOSURE TO CARBON MONOXIDE. RESCUE PERSONNEL SHOULD BE EQUIPPED WITH SELF-CONTAINED BREATHING APPARATUS AND BE COGNIZANT OF EXTREME FIRE AND EXPLOSION HAZARD.**

5. Fire Fighting Measures

Conditions of Flammability: Flammable gas		
Flash point: Not Available	Method: Not Applicable	Autoignition: Temperature: 116 °F (639 °C)
LEL(%): 12.5		UEL(%): 74.0
Hazardous combustion products: None		
Sensitivity to mechanical shock: None		
Sensitivity to static discharge: Not Available		

FIRE AND EXPLOSION HAZARDS:
Having almost the same density as air, it will not diffuse by rising as with some lighter flammable gases such as hydrogen or natural gas (methane). Flammable in air over a very wide range. It reacts violently with oxygen difluoride and barium peroxide.

EXTINGUISHING MEDIA:
Water, dry chemical, carbon dioxide.

FIRE FIGHTING INSTRUCTIONS:
If possible, stop flow of gas; use water spray to cool surrounding containers.

6. Accidental Release Measures

Evacuate all personnel from affected area. Use appropriate protective equipment. If leak is in user's equipment, be certain to purge piping with inert gas prior to attempting repairs. If leak is in container or container valve, contact the appropriate emergency telephone number listed in Section 1 or call your closest BOC location.

7. Handling and Storage

Electrical Classification:
Class 1, Group C

BEST ORIGINAL COPY

Earth-ground and bond all lines and equipment associated with the carbon monoxide system. Electrical equipment should be non sparking or explosion proof.

000014

MSDS: G-112
Revised: 6/7/96

PRODUCT NAME: CARBON MONOXIDE

Carbon Monoxide can be handled in all commonly used metals up to approximately 500 psig (3450 kPa). Above that pressure it forms toxic and corrosive carbonyl compounds with some metals. Carbon steels, aluminum alloys, copper and copper alloys, low carbon stainless steels and nickel-based alloys such as Hastelloy A, B & C are recommended for higher pressure applications.

Protect cylinders from physical damage. Store in cool, dry, well-ventilated areas away from heavily trafficked areas and emergency exits. Do not allow the temperature where cylinders are stored to exceed 130°F (54°C). Cylinders should be stored upright and firmly secured to prevent falling or being knocked over. Full and empty cylinders should be segregated. Use a "first in-first out" inventory system to prevent full cylinders being stored for excessive periods of time. Post "NO SMOKING OR OPEN FLAMES" signs in the storage area or use area. There should be no sources of ignition in the storage area or use area.

Use only in well-ventilated areas. Valve protection caps must remain in place unless container is secured with valve outlet piped to use point. Do not drag, slide or roll cylinders. Use a suitable hand truck for cylinder movement. Use a pressure reducing regulator when connecting cylinder to lower pressure (<3000 psig) piping or systems. Do not heat cylinder by any means to increase the discharge rate of product from the cylinder. Use a check valve or trap in the discharge line to prevent hazardous back flow into the system.

ENGINEERING CONTROLS:

Hood with forced ventilation. Use local exhaust to prevent accumulation above the exposure limit. Use general mechanical ventilation in accordance with electrical codes.

8. Exposure Controls, Personal Protection

EXPOSURE LIMITS¹:

INGREDIENT	% VOLUME	PEL-OSHA ²	TLV-ACGIH ³	LD ₅₀ or LC ₅₀ Route/Species
Carbon Monoxide FORMULA: CO CAS: 630-08-0 RTECS #: FG3500000	100.0	50 ppm TWA	25 ppm TWA	LC ₅₀ 1807 ppm/4H (rat)

¹ Refer to individual state or provincial regulations, as applicable, for limits which may be more stringent than those listed here.

² As stated in 29 CFR 1910, Subpart Z (revised July 1, 1993)

³ As stated in the ACGIH 1994-1995 Threshold Limit Values for Chemical Substances and Physical Agents.

EYE/FACE PROTECTION:

Safety goggles or glasses.

SKIN PROTECTION:

Any material protective gloves.

RESPIRATORY PROTECTION:

Positive pressure air line with full-face mask and escape bottle or self-contained breathing apparatus should be available for emergency use.

OTHER/GENERAL PROTECTION:

Safety shoes.

BEST ORIGINAL COPY

000015

PRODUCT NAME: CARBON MONOXIDE

9. Physical and Chemical Properties

PARAMETER	VALUE	UNITS
Physical state (gas, liquid, solid)	: Gas	
Vapor pressure	: >220.4	psia
Vapor density (Air = 1)	: Not Available	
Evaporation point	: Not Available	
Boiling point	: -312.7	°F
	: -191.5	°C
Freezing point	: -337.1	°F
	: -205.1	°C
pH	: Not Available	
Specific gravity	: 0.96	
Oil/water partition coefficient	: Not Available	
Solubility (H2O)	: Very slight	
Odor threshold	: Not Applicable	
Odor and appearance	: Odorless; colorless gas	

10. Stability and Reactivity

STABILITY:

Stable

INCOMPATIBLE MATERIALS:

Oxidizers

HAZARDOUS DECOMPOSITION PRODUCTS:

Carbon dioxide

HAZARDOUS POLYMERIZATION:

Will not occur.

11. Toxicological Information

REPRODUCTIVE:

Inhalation of 150 ppm carbon monoxide for 24 hours by pregnant rats produced cardiovascular and behavioral defects in offspring. Toxic effects to fertility were observed in female rats exposed to 1 mg/m³ for 24 hours. Similar effects observed in other mammalian species.

MUTAGENIC:

Genetic changes observed in mammalian cell assay systems at exposures of 1500 to 2500 ppm for 10 minutes.

OTHER:

Degenerative changes to the brain in rats chronically exposed to 30 mg/m³.

12. Ecological Information

No data given.

BEST ORIGINAL COPY

000016

MSDS: G-112
Revised: 6/7/96

PRODUCT NAME: CARBON MONOXIDE

13. Disposal Considerations

Do not attempt to dispose of residual waste or unused quantities. Return in the shipping container PROPERLY LABELED, WITH ANY VALVE OUTLET PLUGS OR CAPS SECURED AND VALVE PROTECTION CAP IN PLACE to BOC Gases or authorized distributor for proper disposal.

14. Transport Information

PARAMETER	United States DOT	Canada TDG
PROPER SHIPPING NAME:	Carbon Monoxide	Carbon Monoxide
HAZARD CLASS:	2.3	2.3 (2.1)
IDENTIFICATION NUMBER:	UN 1016	UN 1016
SHIPPING LABEL:	POISON GAS, FLAMMABLE GAS	POISON GAS, FLAMMABLE GAS

Additional Marking Requirement: "Inhalation Hazard"

Additional Shipping Paper Description Requirement: "Poison-Inhalation Hazard, Zone D"

15. Regulatory Information

SARA TITLE III NOTIFICATIONS AND INFORMATION

SARA TITLE III - HAZARD CLASSES:

Acute Health Hazard
Chronic Health Hazard
Fire Hazard
Sudden Release of Pressure Hazard

16. Other Information

Compressed gas cylinders shall not be refilled without the express written permission of the owner. Shipment of a compressed gas cylinder which has not been filled by the owner or with his/her (written) consent is a violation of transportation regulations.

DISCLAIMER OF EXPRESSED AND IMPLIED WARRANTIES:

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained herein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequences of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

BEST ORIGINAL COPY

000017

Submission End

000018

AM



OLSSON, FRANK AND WEEDA, P. C.

ATTORNEYS AT LAW

SUITE 400

1400 SIXTEENTH STREET, N.W.

WASHINGTON, D. C. 20036-2220

(202) 789-1212

FACSIMILE (202) 234-3550

PHILIP C. OLSSON
RICHARD L. FRANK
DAVID F. WEEDA (1948-2001)
DENNIS R. JOHNSON
ARTHUR Y. TSIEN
JOHN W. BODE*
STEPHEN D. TERMAN
MARSHALL L. MATZ
MICHAEL J. O'FLAHERTY
DAVID L. DURKIN
NEIL F. O'FLAHERTY
PAMELA J. FURMAN
BRETT T. SCHWEMER
TISH E. PAHL
ROBERT A. HAHN

STEPHEN L. LACEY
EVAN P. PHELPS
VALERIE B. SOLOMON
JOLYDA O. SWAIM
KATHRYN E. BALMFORD
COUNSEL
NAOMI J. L. HALPERN
OF COUNSEL
JUR. T. STROBOS
JACQUELINE H. EAGLE
KENNETH D. ACKERMAN
MARK L. ITZKOFF
DAVID A. BIEGING
SR. GOVERNMENT AFFAIRS ADVISOR
JOHN R. BLOCK
CHARLES W. STENHOLM
BRIAN E. JOHNSON
SALLY S. DONNER

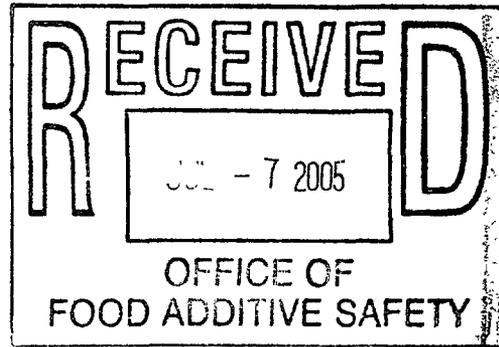
Sender's Direct Phone (202) 518-6327
Sender's Direct Facsimile (202) 234-2686

*PRACTICE WITHIN THE DISTRICT OF COLUMBIA
IS LIMITED TO MATTERS AND PROCEEDINGS
BEFORE FEDERAL COURTS AND AGENCIES

June 29, 2005

BY FACSIMILE AND U.S. MAIL

Dr. Lane A. Highbarger
U.S. Food and Drug Administration
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Harvey W. Wiley Federal Building
5100 Paint Branch Parkway (HFS-255)
College Park, MD 20740-3835



Re: GRAS Notification 167

Dear Dr. Highbarger:

On behalf our client, Tyson Foods, Inc., we are submitting this letter to clarify the intended conditions of use for carbon monoxide (CO) in the modified atmosphere packaging (MAP) described in GRAS Notification 167 (GRASN 167).

As described in the GRAS Notice, Tyson Foods will be using MAP containing CO for packaging red meat products. To ensure that the CO does not result in consumers storing meat at refrigerated temperatures for excessive periods, the products will be labeled with a "use or freeze by" date. Under this dating system, consumers will be instructed to use or freeze the meat products by a specific date. For whole muscle cuts, the "use or freeze by" date will not exceed 35 days from the date of packaging; the "use or freeze by" date for ground meat products will not exceed 28 days.

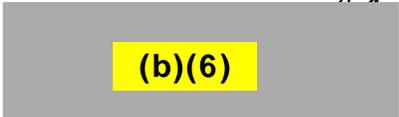
BEST ORIGINAL COPY

000019

Letter to Dr. Lane A. Highbarger
June 29, 2005
Page 2

We trust that you now have sufficient information to complete your review of the Tyson Foods GRAS notification. Should you have any additional questions, please do not hesitate to contact us.

Sincerely,


(b)(6)

Mark L. Itzkoff

MLI:jdm

cc: Dr. Robert Post
U.S. Department of Agriculture (by Fax)

BEST ORIGINAL COPY

000020

OLSSON, FRANK AND WEEDA, P. C.

PHILIP C. OLSSON
RICHARD L. FRANK
DAVID F. WEEDA (1948-2001)
DENNIS R. JOHNSON
ARTHUR Y. TSIEN
JOHN W. BODE*
STEPHEN D. TERMAN
MARSHALL L. MATZ
MICHAEL J. O'FLAHERTY
DAVID L. DURKIN
NEIL F. O'FLAHERTY
PAMELA J. FURMAN
BRETT T. SCHWEMER
TISH E. PAHL
ROBERT A. HAHN

ATTORNEYS AT LAW
SUITE 400
1400 SIXTEENTH STREET, N.W.
WASHINGTON, D. C. 20036-2220
(202) 789-1212
FACSIMILE (202) 234-3550

Sender's Direct Phone (202) 518-6327
Sender's Direct Facsimile (202) 234-2686

STEPHEN L. LACEY
EVAN P. PHELPS
VALERIE B. SOLOMON
JOLYDA O. SWAIM
KATHRYN E. BALMFORD
COUNSEL
NAOMI J. L. HALPERN
OF COUNSEL
JUR. T. STROBOS
JACQUELINE H. EAGLE
KENNETH D. ACKERMAN
MARK L. ITZKOFF
DAVID A. BIEGING
SR. GOVERNMENT AFFAIRS ADVISOR
JOHN R. BLOCK
CHARLES W. STENHOLM
BRIAN E. JOHNSON
SALLY S. DONNER

*PRACTICE WITHIN THE DISTRICT OF COLUMBIA
IS LIMITED TO MATTERS AND PROCEEDINGS
BEFORE FEDERAL COURTS AND AGENCIES

June 29, 2005

BY FACSIMILE AND U.S. MAIL

Robert C. Post, Ph.D.
Director
Labeling and Consumer Protection Staff
U.S. Department of Agriculture
Room 602
300 12th Street S.W.
Washington, D.C. 20250

Re: GRAS Notification 167

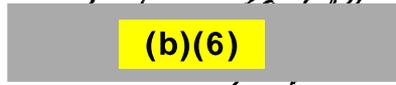
BEST ORIGINAL COPY

Dear Dr. Post:

On behalf of our client, Tyson Foods, Inc., we are hereby forwarding a copy of a clarification to the above-referenced GRAS notification which we submitted today. As you can see, Tyson Foods is limiting the use of carbon monoxide described in this GRAS Notice to modified atmosphere packaging applications, and all products are labeled with a "use or freeze by" date.

We trust that USDA will now be able to complete its evaluation of the Tyson Foods GRAS notification. Should you have any questions, please do not hesitate to contact us.

Sincerely,

Mark L. Itzkoff

MLI:jdm
Enclosure

cc: Dr. Lane Highbarger
Food and Drug Administration (by Fax)

000021