UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION,
PESTICIDES, AND TOXIC SUBSTANCES

DATE: May 25, 2006

ACTION MEMORANDUM

SUBJECT: Inert Reassessment -- Two Exemptions from the Requirement of a Tolerance for Propane (CAS Reg. No. 74-98-6) and Two Exemptions from the Requirement of a Tolerance for Butane (CAS Reg. No. 106-97-8)

FROM: Pauline Wagner, Chief Pauline Wagner 5/30/06
Inert Ingredient Assessment Branch
Registration Division (7505C)

TO: Lois A. Rossi, Director
Registration Division (7505C)

I. FQPA REASSESSMENT ACTION

Action: Reassessment of four inert exemptions from the requirement of a tolerance. The reassessment decision is to maintain the inert ingredient tolerance exemptions "as-is."

Chemical: Propane and Butane

CFR: Both propane and butane have tolerance exemptions in 40 CFR part 180.910 and 930.

CAS Registry Number and Name:
1. CAS Name: Propane (CAS Reg. No. 74-98-6)
2. CAS Name: Butane (CAS Reg. No. 106-97-8)

Use Summary: Propane and butane are used as propellants for aerosol shaving creams, skin fresheners, makeup, hair conditioners, deodorants, cosmetics and personal hygiene products. As inert ingredients in pesticide products, propane and butane are also used as propellants.

List Reclassification Determination: The current List Classification for butane is 4B and it will remain this category. The current List Classification for propane is List 3. Because EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to propane when used as inert ingredients in pesticide formulations, the List Classification for propane will change from List 3 to List 4B.

II. MANAGEMENT CONCURRENCE

I concur with the reassessment of the two exemptions from the requirement of a tolerance for propane (CAS Reg. No. 74-98-6) and the two exemptions from the requirement of a tolerance for butane (CAS Reg. No. 106-97-8), and with the List reclassification determinations, as described above. I consider the 2 tolerance exemptions for butane established in 40 CFR part 180.910 and 930, and the 2 tolerance exemptions for propane established in 40 CFR part 180.910 and 930 to be reassessed for purposes of FFDCA's section 408(q) as of the date of my signature, below. A Federal Register Notice regarding this tolerance exemption reassessment decision will be published in the near future.

Lois A. Rossi, Director
Registration Division

5/30/06
Date:

cc: Debbie Edwards, SRRD
Joe Nevola, SRRD

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SUBJECT: Reassessment of Two Exemptions from the Requirement of a Tolerance for Propane (CAS Reg. No. 74-98-6) and Two Exemptions from the Requirement of a Tolerance for Butane (CAS Reg. No. 106-97-8)

FROM: Byron T. Backus, Ph.D., Toxicologist Byron T. Backus 5/30/06
Technical Review Branch
Registration Division (7505P)

TO: Pauline Wagner, Chief
Inert Ingredient Assessment Branch
Registration Division (7505P)

BACKGROUND

Attached is the science assessment for propane and butane (butane). This assessment summarizes available information on the use, physical/chemical properties, toxicological effects, exposure profile, and environmental fate and ecotoxicity of propane and butane. The purpose of this document is to reassess the existing exemptions from the requirement of a tolerance for residues of propane and butane when used in accordance with good agricultural practices as inert (or occasionally active) ingredients in pesticide formulations as required under the Food Quality Protection Act (FQPA).

EXECUTIVE SUMMARY

This report evaluates propane and butane, pesticide inert ingredients which each have two exemptions from the requirement of a tolerance for their residues when used in accordance with good agricultural practice as inert ingredients (propellants) in pesticide formulations applied to growing crops or raw agricultural commodities after harvest (40 CFR 180.910) and to animals (40 CFR 180.930).

Both propane and butane are odorless and highly flammable/explosive when mixed with air. The major exposure route for both propane and butane is by inhalation. Toxicity from butane or propane is observed only at high levels and via the inhalation route of exposure. Available studies do not suggest effects on the reproductive or endocrine systems. The current toxicological information, therefore, does not suggest any concerns for susceptibility in the young. The occupational exposure threshold limit values (TLVs) are 2,500 ppm for propane and 800 ppm for butane. The current OSHA Permissible Exposure Limit (PEL) for propane is 1,000 ppm (=1,800 mg/m3) for an 8-hour day. The NIOSH Immediate Danger to Life and Health (IDLH) limit for propane is 2,100 ppm. In addition, both propane and butane are listed by the Food and Drug Administration under 21 CFR 184.1 as generally recognized as safe (GRAS) substances when added directly as propellants, aerating agents, and gases [as defined in 21 CFR 170.3(o)(25)] to human food.

EPA expects that the potential for dietary (food and drinking water) exposures would be low because both propane and butane are gases and are rapidly lost to the atmosphere after application. There is a hazard from flammability; most of these products typically contain a small amount of these substances because of their very low flash points. The very flammable nature of these chemicals requires that pesticide products bear label language directing users to use adequate ventilation when applying the product, which will serve to reduce the potential for inhalation exposures from residential uses.

Taking into consideration all available toxicity and exposure information on propane and butane, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure from their use as inert ingredients (propellants) in pesticide formulations when considering dietary exposure and all other nonoccupational sources of pesticide exposure for which there is reliable information. Therefore, it is recommended that the exemptions from the requirement of a tolerance established for residues of propane and butane under 40 CFR 180.910 and 930 can be considered reassessed as safe under section 408(q) of the Federal Food, Drug, and Cosmetic Act (FFDCA).

I. Introduction

Propane [CAS No: 74-98-6] and butane [CAS No: 106-97-8] are being evaluated as part of EPA's tolerance reassessment process for inert ingredients. The information presented in this report was derived from published and unpublished studies identified in searches of major bibliographic databases, and reliable secondary references.

Propane and butane are produced in significant amounts as byproducts from various refinery processes including catalytic cracking and crude distillation. Both can be used (either individually or in combination) to produce liquefied petroleum gas (LPG). Propane's concentration ranges from ~3 to 18%; and butane's range is presumably similar. Both are emitted into the atmosphere from furnaces, automobile exhausts, and natural gas sources. Both occur at trace levels in human expired air. Butane has been detected in human breath samples at concentrations between 1 to 10 ppb (Fenske & Paulson, 1999).

Both are odorless, highly flammable and explosive when mixed with air. Both are used as aerosol components and as fuel sources. In industry, they are used as components of liquid petroleum gas for commercial and industrial applications. Propane is used as a feedstock in thermal cracking processes used to manufacture ethylene and propylene. Both are used as basic materials in chemical synthesis for oxidation, alkylation, nitration, and chlorination, and as aerosol propellants to replace chlorofluorocarbons. Both are used as solvents and extractants in deasphalting and degreasing of crude oils. With sufficient oxygen both burn to form carbon dioxide and water, but carbon monoxide is formed when there are inadequate amounts of oxygen combustion.

II. Use Information

A. Pesticides

Propane and butane are used as inert ingredients (propellants) only, and there are no currently registered pesticide products containing either one or both as active ingredients. The tolerance exemptions for propane and butane are shown in Table 1 below.

Table 1. Tolerance Exemptions Being Reassessed in this Document

CFR Citation				CAS Reg. No.
40 CFR 180	Inert Ingredients	Limits	Uses	
.910[a] .930[b]	Propane	----	Propellant	74-98-6 Propane
.910[a] .930[b]	Butane	---	Propellant	106-97-8 Butane

[a]Residues listed in 40 CFR 180.910 are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest.
[b]Residues listed in 40 CFR 180.930 are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to animals.

B. Other Uses

Propane and butane are also used as propellants for aerosol shaving creams, skin fresheners, makeup, hair conditioners, deodorants, cosmetics and personal hygiene products. In these products, the amount of propane or butane is typically less than 5%, although a single personal cleanliness product is listed as containing 10 to 25% butane (Moore, 1982). In addition, both propane and butane are listed by the Food and Drug Administration under 21 CFR 184.1 as generally recognized as safe (GRAS) substances when added directly as propellants, aerating agents, and gases [as defined in 21 CFR 170.3(o)(25)] to human food.

Table 2. Food Additives Permitted For Direct Addition To Food For Human Consumption

Name	21 CFR	Use Pattern
butane (and isobutane)	184.1165	Substance added directly to human food GRAS
propane	184.1655	Substance added directly to human food GRAS

III. Physical and Chemical Properties

Some of the physical and chemical characteristics of propane, along with its structure and nomenclature, are given in Table 3. Characteristics of butane are given in Table 4.

Table 3. Physical and Chemical Properties of Propane

Parameter	Value	Reference
Structure	H H H | | | H-C-C-C-H | | | H H H	HSDB
CAS #	74-98-6	
Molecular Formula	C_3H_8	
Molecular Weight	44.09	
Common Names	Propyl hydride; Dimethylmethane, N-propane	
Physical State	Colorless, odorless gas	
Melting Point	-189.7°C	
Boiling Point	-42.1°C	
Flash Point	-140.4°C	
Vapor Pressure at 25°C	760 mm Hg	
Viscosity	79.5 micropoises (17.9°C); 100.9 micropoises (100.4°C); 125.1 micropoises (199.3°C)	
Surface tension at -1°C	16 dynes/cm=0.016 N/m	
Index of refraction at 20°C	1.2898	
Relative Vapor Density (air=1)	1.56	
Octanol/water partition coeff.: Log K_{ow}	2.36	
Solubility at 25°C	62.4 ppm in water; slightly soluble in acetone; >10% in benzene; >10% in ether; >10% in ethanol; >10% in chloroform.	
Density at -45°C	0.5853	
Vapor density at 0°C	1.56 (air=1)	
Conversion Factors at 20°C	1 mg/m³ = 0.54 ppm 1 ppm = 1.84 mg/m³	
Other	Flammable; burns with a luminous, smoky flame	

Table 4. Physical and Chemical Properties of Butane

Parameter	Value	Reference
Structure	H H H H | | | | H-C-C-C-C-H | | | | H H H H	HSDB
CAS #	106-97-8	
Molecular Formula	C_4H_{10}	
Molecular Weight	58.12	
Common Names	Butyl hydride, Methylethylmethane, Pyrofax, Hydrocarbon propellant A-17, R-600	
Physical State	Colorless gas with a faint, disagreeable ("natural gas") odor	
Melting Point	-138.4°C	
Boiling Point	-0.5°C	
Flash Point	-60°C	
Vapor Pressure at 25°C	760 mm Hg	
Viscosity	(At 1.013 bar and 0°C): 0.0000682 Poise	
Surface tension at -1 °C	14.7 dynes/cm=0.0147 N/m	
Index of refraction at 20°C	1.3326	
Relative Vapor Density (air=1)	2.0	
Octanol/water partition coeff.: Log K_{ow}	2.89	
Solubility at 20°C	In water: 0.0061 g/100 mL; soluble in ether and chloroform;	
Density at -1°C	0.60	
Conversion Factors at 20°C	1 mg/m^3 = 0.41 ppm 1 ppm = 2.42 mg/m^3	
Other	Flammable; burns with a luminous, smoky flame	

IV. Hazard Assessment

To assess the toxicity posed by the use of propane and butane, either singly or in combination, as inert ingredients in pesticide formulations, the Environmental Protection Agency (EPA or the Agency) has largely relied on information contained in the following documents: U.S. EPA High Production Volume (HPV) Challenge Program: Robust Summaries & Test Plans: Petroleum Gas, Appendix 3 (Summary prepared by the American Petroleum Institute, last updated 15 August 2000); and Final Report of the Safety Assessment of Isobutane, Isopentane, butane, and Propane (Moore, 1982).

Data requirements to determine a pesticide's flammability are specified in the regulations at 40 CFR 158.190. The OPPTS Harmonized Test Guidelines Series 830, Product Properties (830-6315) covers the flash point and flame extension of a product.

The flame extension test is required for aerosol products. The hazards associated with a pesticide product's flammability are addressed by labeling (Refer to the EPA Pesticide Label Review Manual at http://www.epa.gov/oppfead1/labeling/lrm/chap-09.htm).

A. Toxicological Data

Propane – overview: Propane is a gas at normal temperatures (the boiling point is -42.1°C), therefore, inhalation is the major route by which it is absorbed systemically. Compared to the respiratory route, the dermal penetration of propane can be considered to be very low. Propane is a simple asphyxiant like methane and ethane. Based on animal studies, propane is much less toxic than its next higher homolog, *butane*. Propane also possesses anesthetic properties, but is much less potent than other higher molecular weight aliphatics. Like a number of other low molecular weight alkanes, high concentrations of propane have been shown to sensitize the myocardium to epinephrine-induced cardiac arrhythmias.

Propane – acute toxicity: For inhalation toxicity, the U.S. EPA High Production Volume (HPV) Challenge Program (2000) gives a Threshold Limit Value (TLV) of 2,500 ppm, listing the critical effect as simple asphyxiant. The same source also summarizes an inhalation toxicity study with rats, in which groups of either 6 males or 6 females were exposed for effects on the central nervous system (CNS) over a 10-minute exposure period. The EC_{50} CNS effect (10-min) was calculated. An LC_{50} (15-min) was also determined. Propane caused CNS depression. Signs of intoxication were slight ataxia, loss of righting reflex, loss of movement, narcosis, and shallow respiration, with death resulting from respiratory depression. The LC_{50} (15 min.) was >800,000 ppm [= 1,442,847 mg/m^3]. Recovery from a non-lethal exposure was rapid and the rats appeared normal within 10 minutes. When death occurred, it was during exposure, never afterwards. The calculated EC_{50} (with 95% confidence limits) based on CNS depression (after 10 min.) was 280,000 (220,000-350,000) ppm.

Propane – chronic toxicity: Meltzer *et al.* (1977) studied the effects of an aerosol spray deodorant containing a mixture of isobutene and propane at a concentration of 64.5% by weight (the concentration of propane was not reported) on nine male and nine female stump-tail monkeys. Animals were divided into three groups (A, B, and C) with 3/sex/group. Group A was the control, Group B was exposed to air drawn from a mixing chamber which received a 1 sec spray of the test material at 42 min intervals for 6 hours (0.5 mg test material/L/exposure), and Group C received a 5 sec spray of the test material at 21 min intervals for 6 hrs (5.0 mg test material/L/exposure). Exposures continued for 90 days. All animals survived the experiment and showed no changes in behavior, body weight, hematology, biochemistry, or urinalysis. Electrocardiograms and tidal volume rates showed no significant changes, and gross and microscopic examinations showed no abnormalities.

The Cosmetic, Toiletry, and Fragrance Association (CTFA), in a study cited by the Cosmetic Ingredient Review (CIR) Expert Panel, carried out a 90-day subchronic inhalation study with cynomolgus monkeys using an antiperspirant containing propane as a propellant at greater than 50% concentration. Twenty-one animals were exposed to 750 ppm of the gas for 90 consecutive days. No toxicity was observed in this study.

Butane – overview: Because butane is a gas at normal temperatures (the boiling point is -0.5°C), inhalation is the major route for systemic toxicity. In acute inhalation toxicity studies, butane has low toxicity for acute inhalation, although animals exposed to butane exhibited anesthesia and CNS depression. In laboratory animals, butane has been shown to sensitize the myocardium to epinephrine-induced cardiac arrhythmias. The occupational exposure TLV is 800 ppm, with narcosis as the critical effect.

Butane – acute toxicity: Butane has a relatively low acute inhalation toxicity in laboratory animals (see Table 5, below).

Table 5. Acute toxicity values for butane in laboratory animals

Species	Route	Effect/Endpoint	Reference
Rat	Inhalation	4-hr LC_{50}= 658 mg/L	HSDB
Mouse	Inhalation	2-hr LC_{50}= 680 mg/L; a concentration of 308 mg/L caused light anesthesia within 25 minutes, and an exposure to 521 mg/L had a similar effect within one minute.	
Dog	Inhalation	Lethal Concentration: 474-592 mg/L	

Butane Subchronic/Chronic Toxicity: In a 21-day inhalation toxicity study of a mixture of butane, isobutene, n-pentane and isopentane, containing 25% of each, there was no indication of toxicity at up to 11.8 mg/L, the highest concentration tested. The study was performed on Sprague-Dawley rats exposed to this mixture 6 hours per day over three weeks for a total of 15 exposures (Berzine, as cited in HSDB).

The subchronic toxicity of a 50:50 mixture of butane and n-pentane was evaluated by inhalation exposure of male and female F-344 rats (20 males and 10 females/group) at concentrations of 1,000 and 4,500 ppm, while a control group of 40 males and 20 females received filtered air. All rats were exposed for 6 hours/day, 5 days/week. Half the males from each group were sacrificed and necropsied after 20 exposures. The remaining rats were sacrificed and necropsied after 65 exposures. All rats survived to scheduled sacrifice. Male rats (3/10) exposed to 4,500 ppm and male (2/10) and female (1/10) rats exposed to 1,000 ppm exhibited hunched posture and/or lethargy which persisted 1 to 3 days following week 6. Both males and females exposed to the hydrocarbon mixture showed crusted eyes and swollen eyelids, with the highest incidence observed in females at 4,500 ppm. Body weights were significantly decreased in both sexes at both exposure levels compared to controls by week 3 and 4. Female body weights remained depressed throughout the course of the study, while males seemed to recover during week 11. There was no apparent dose-response relationship. Liver and kidney weights from all treated rats were comparable to those of the controls at both 4 and 13 weeks. Gross lesions observed during necropsy were unrelated to treatment (IIT Research Institute, as cited in HSDB).

Propane and Butane – genetic toxicity: In studies by the Stanford Research Institute (SRI), cited by the CIR Expert Panel, strains of *Salmonella typhimurium* were exposed to various concentrations of propane with and without activation. No mutagenicity was reported.

Kirwin and Thomas (1980, as cited by the EPA/OPPT High Production Volume (HPV) Challenge Program Robust Summaries & Test Plans), evaluated the mutagenic activity of both propane and butane in the Ames *Salmonella typhimurium* assay (strains TA98, TA100, TA1535, TA1537 and TA1538) using various vapor concentrations, with and without metabolic activation (rat S9). Six different compositions of hydrocarbon gases were tested, including a mixture that was predominately propane (>99.9%) with traces of iso-butane and butane, and a mixture that was mostly butane (99.7%) with a slight amount (0.3%) of isobutane. Duplicate plates seeded with the appropriate *Salmonella typhimurium* strains were placed in desiccators from which air was withdrawn and replaced by the gas mixtures. Gas test concentrations were 10, 20, 30, 40 and 50% in air. The plates were exposed for 6 hours to the gas mixtures in the sealed desiccators, after which they were removed and incubated at 37°C for 40-45 hours. The numbers of histidine revertants were then counted and recorded. Negative and positive (methylene chloride) controls were also evaluated. The positive control (methylene chloride) was mutagenic in strains TA98 and TA100, and was slightly mutagenic in TA1535. Neither propane nor butane was toxic or mutagenic at any of the concentrations tested.

Shimizu *et al.* (1985) evaluated butane in an Ames assay (*Salmonella typhimurium* strains TA100, TA1535, TA98, TA1537 and TA1538, and *E. coli* WP2 uvrA) in the presence and absence of metabolic activation (rat S9) at butane concentrations ranging from 250 to 10,000 ppm, with no indication of toxicity or mutagenicity in any of the test strains. The positive controls gave appropriate results.

Butane was negative in a sex-linked recessive lethal mutation assay in *Drosophila melanogaster* with inhalation exposure to 350,000 ppm (Foureman *et al.,* 1994).

B. Metabolism and Pharmacokinetics

Propane and butane metabolism: Tsukamoto *et al.* (1985) reported that, following inhalation exposure, mice metabolized propane to isopropanol and acetone, and butane to sec-butanol and methyl ethyl ketone. *In vitro* reactions with liver microsomes produced isopropanol from propane and sec-butanol from butane. It was assumed that these hydrocarbons were first converted to (omega-

1)-alcohols by the microsomal enzyme system and then to corresponding ketones by alcohol dehydrogenase.

Butane Absorption/Distribution: Inhalation studies in which rats and mice were exposed to lethal concentrations (27.8-29%) revealed that butane is absorbed and distributed to various tissues. After 4 hr of respiratory exposure, surviving rats were sacrificed. Concentrations of butane were highest in perinephric fat (2086 ppm), followed by brain (750 ppm), spleen (522 ppm), liver (492 ppm), and kidney (441 ppm). In mice exposed to 2 hr of butane vapors, the brain levels of butane were found to be 779 ppm. In both rats and mice the brain levels of butane correlated with the degree of CNS depression. Dermal absorption of butane vapors has not been reported. However, dermal penetration of butane would not be expected to occur to any significant degree since skin contact is transient because of butane's volatility (Snyder, as cited in HSDB).

Butane undergoes hydroxylation in the presence of rat liver microsomes to yield 2-butanol as the major metabolite. In mammals, 2-butanol would be expected to be eliminated in the expired air. (Snyder, as cited in HSDB).

C. Special Considerations for Infants and Children

Toxicity from butane or propane is observed only at high levels and via the inhalation route of exposure. Available studies do not suggest effects on the reproductive or endocrine systems. The current toxicological information, therefore, does not suggest any concerns for susceptibility in the young. Considering the available toxicity information of these chemicals, there is no concern, at this time, for increased sensitivity to infants and children to butane and propane when used as an inert ingredient in pesticide formulations. For the same reason, a safety factor analysis has not been used to assess risk and, therefore, the additional tenfold safety factor for the protection of infants and children is also unnecessary.

V. Environmental Fate Characterization and Drinking Water Considerations

According to the U.S. EPA High Production Volume Robust Summaries & Test Plans for Petroleum Gas (2000) both propane and butane are readily degraded in contact with hydroxyl radicals in the troposphere, under the influence of sunlight. The half-lifes are calculated as 7 days for propane and 3.2 days for butane (as compared with 960 days for methane and 30 days for ethane). The same reference also states that in the event of an accidental release of C_1 to C_4 hydrocarbons to the environment, all of the material will be released to the air due to the volatility of the hydrocarbons (100% of the final distribution will be in the atmosphere). This is also consistent with the relatively low solubilities of both substances in water (propane: 0.07 g/100 mL at 20°C; butane: 0.0061 g/100 mL at 20°C). Considering the physical-chemical characteristics of propane and butane, contributions to drinking water are not expected from their use as inert ingredients in pesticide products.

According to the U.S. EPA High Production Volume Robust Summaries & Test Plans for Petroleum Gas (2000) the ability of bacteria to use C_1 to C_4 hydrocarbons as a carbon source has been demonstrated in a number of studies. In particular, Vestal and Perry (1970) found that ethane, propane and butane promoted the growth of *Mycobacterium vaccae*, suggesting that these hydrocarbons are biodegradable. By contrast, studies by Wanatabe & Takesue (1971) and by Rode and Foster (1965) have shown that butane is also able to inhibit the growth of certain bacteria, molds, fungi and plant seeds.

VI. Exposure Assessment

The major exposure route for both propane and butane is by inhalation. The occupational exposure threshold limit values (TLVs) are 2,500 ppm for propane and 800 ppm for butane. The current OSHA Permissible Exposure Limit (PEL) for propane is 1,000 ppm (=1,800 mg/m^3) for an 8-hour day. The NIOSH Immediate Danger to Life and Health (IDLH) limit for propane is 2,100 ppm.

Dietary

EPA expects that any exposures from food would be low because both propane and butane are gases and are rapidly lost to the atmosphere after application. For this reason, and because both have low solubility in water, the use of these substances as propellants in pesticide products is not expected to contribute to drinking water exposure. Therefore, dietary exposures of concern from food and drinking water are not likely from the use of propane and/or butane as propellants in pesticide formulations.

Residential

Propane and/or butane may be present as propellants in pesticide formulations registered for use in and around the home. Most of these products typically contain 5% (by weight) or less of these substances because of their very low flash points. The flammable nature of these chemicals also requires that products bear label language directing users to use adequate ventilation when applying the product, which will serve to reduce the potential for exposure. Therefore, inhalation exposures of concern from residential uses of propane and butane as inert ingredients in pesticide products are not likely.

VII. Aggregate Exposures

In examining aggregate exposure, the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other nonoccupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

For propane and butane, a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) is appropriate given the lack of human health concerns associated with exposure to these chemicals as inert ingredients in pesticide formulations.

VIII. Cumulative Exposure

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to propane and butane and any other substances and, these materials do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that propane and butane have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

IX. Human Health Risk Characterization

Both propane and butane are odorless and highly flammable/explosive when mixed with air. The major exposure route for both propane and butane is by inhalation. Toxicity from butane or propane is observed only at high levels. The occupational exposure threshold limit values (TLVs) are 2,500 ppm for propane and 800 ppm for butane. The current OSHA Permissible Exposure Limit (PEL) for propane is 1,000 ppm (=1,800 mg/m3) for an 8-hour day. The NIOSH Immediate Danger to Life and Health (IDLH) limit for propane is 2,100 ppm.

EPA considers it unlikely that propane and/or butane will pose a health risk for the general population from their use as propellants in pesticide formulations. Because both propane and butane are gases at normal temperatures and atmospheric pressure, there would likely be only an extremely small dietary exposure from their use as propellants in pesticide formulations applied to growing crops or raw agricultural commodities, or when applied to animals. For residential exposure, the flammable nature of these chemicals also requires that products bear label language directing users to use adequate ventilation when applying the product, which will serve to reduce the potential for inhalation exposure.

Taking into consideration all available information on butane and propane, it has been determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to butane and propane when considering exposure through food commodities and all other non-occupational sources for which there is reliable information. Therefore, it is recommended that the two exemptions from the requirement of a tolerance established for residues of butane, and the two exemptions from the requirement of a tolerance established for residues of propane when used as propellants in pesticide products under 40 CFR 180.910 and .930 can be considered reassessed as safe under section 408(q) of the FFDCA.

X. Ecotoxicity and Ecological Risk Characterization

From the U.S. EPA High Production (HPV) Challenge Program Robust Summaries & Test Plans: Petroleum Gas (2000): "...it is now considered that aquatic toxicity of petroleum gases is not applicable." The same source also gives acute toxicity to aquatic invertebrates, aquatic plants and aquatic organisms as not applicable.

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