EPA-APPROVED KENTUCKY SOURCE—SPECIFIC REQUIREMENTS

Name of source	Permit number	State effective date	EPA approval date	Explanation
*	* * * * *	*		*
Board Order Kosmos Cement Company.	NO_X RACT Plan 05/03/04	05/03/04	05/18/05 [Insert first page number of publication]	
*	* * * * *	*		*

(e) * * *

EPA-APPROVED KENTUCKY NON-REGULATORY PROVISIONS

Name of regulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approval date	Explanation
*	* * * * *	*		*
Louisville 1-Hour Ozone Maintenance Plan.	Jefferson County and portions of Bullitt and Oldham Counties	11/1/03	05/18/05 [Insert first page number of publication]	
*	* * * * *	*		*

[FR Doc. 05–9905 Filed 5–17–05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 80

[OPP –2005–0109; FRL–7711–4]

Dimethyl Ether; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of dimethyl ether or methane, oxybis- as an inert ingredient (propellant) in pesticide formulations applied to growing crops or to raw agricultural commodities (RAC) after harvest. The DuPont Company, DuPont Fluoroproducts submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of dimethyl ether.

DATES: This regulation is effective May 18, 2005. Objections and requests for hearings must be received on or before July 18, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit XIV. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket identification (ID) number OPP–2005–0109. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6304; e-mail address: *boyle.kathryn@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of

entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Electronic Documents and Other Related Information?

In addition to using EDOCKET at *(http://www.epa.gov/edocket/)*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of September 27, 2000 (65 FR 58078) (FRL–6742–4), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (6E4785) by the DuPont Company, DuPont Fluoroproducts, Chestnut Run Plaza, P.O. Box 80711, Wilmington, DE, 19880–0711. This notice included a summary of the petition prepared by the petitioner.

The petition requested that 40 CFR 180.1001(c) now redesignated as 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of dimethyl ether (DME), also known as methane, oxybis, (CAS Reg. No. 115–10–6) as an inert ingredient (propellant) in pesticide formulations applied to growing crops or to RAC after harvest. There were no comments received in response to the notice of filing.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Physical/Chemical Properties

The vapor pressure of DME is 4,450 mm Hg @ 25°C. DME exists as a gas at room temperature, thus allowing it to spread and disperse rapidly. DME is soluble in water (7% by weight). The flash point of DME is -41°C or -42°C with flammable limits in air of 3.4% by volume in air (lower limit) and 18.0% (upper limit). DME is slightly heavier than air with a density of 1.92 grams/Liter @ 1 atmosphere and 25°C.

V. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability, and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects identified in DME toxicity studies are discussed in this unit.

A. Review and Evaluation of Five Inhalation Toxicity Studies

The Agency reviewed and evaluated the following five inhalation toxicity studies conducted using DME.

TABLE 1.—DIMETHYL ETHER INHALATION TOXICITY STUDIES

Study Type (Species)	Results
Acute Inhalation (rat)	Doses were 8.4, 12.1, 15.2, 16.9, or 20.5% equivalent to 84,000, 121,000, 152,000, 169,000, or 205,000 part per million (ppm); or 158, 228, 286, 318, or 386 mg/L. LC_{50} = 309 mg/L (Toxicity Category IV) (95% confidence limits of 268 - 382 mg/L) Whole-body inhalation exposure. Clinical signs during exposure included ataxia, anesthesia, coma, head bobbing, paw waving, and heavy or short jerky respirations.
2-Week Inhalation (rat)	Doses were 0, 1, or 5% (v/v) equivalent to 0, 18.8, or 94.1 mg/L NOAEL = Not determined LOAEL = 1% or 18.8 mg/L Whole-body inhalation exposure. LOAEL based on red nasal and ocular discharge, sluggish behavior, salivation, lung noise, wet perineal area, decreased cumulative body weight gains, and decreased thymus and liver weights. Moderate sluggishness occurred briefly at 1% and was very common at 5%.
13 Week Inhalation (rat and hamster)	Doses were 1, 1,000, 5,000, 10,000, or 20,000 ppm equivalent to 0, 1.9, 9.4, 18.8, or 37.7 mg/L. NOAEL = 37.7 mg/L LOAEL = Not Observed Whole body inhalation exposure in both species. There were no treatment-related effects.

TABLE 1.—DIMETHYL ETHER INHALATION TOXICITY STUDIES—Continued

Study Type (Species)	Results
Chronic toxicity/carcinogenicity (rat)	Doses were 0, 0.2, 1.0, or 2.5% equivalent to 0, 2,000, 10,000, or 25,000 ppm; or 0, 3.7, 18.6, and 46.4 mg/L NOAEL = 3.7 mg/L LOAEL = 1% or 18.6 mg/L Whole body inhalation exposure. LOAEL based on decreased survival towards the end of the study and liver angictasis in males. The Office of Pesticide Program Cancer Peer Review Committee concluded that DME should be classified as Group D (not classifiable as to human carcinogenicity) since chronic testing was performed in only one species.
Cardiac sensitization (dog)	Doses were 10, 20, (16.7), or 30 (33.3%) (v/v) equivalent to 100,000, 200,000, or 300,000 ppm. The dogs received an intravenous injection of epinephrine prior to exposure to the DME and a second (challenge) injection after breathing the test compound for five minutes. NOAEL = 10% LOAEL = 16.7% Capable of sensitizing the mammalian heart to epinephrine (development of a cardiac arrhythmia after a challenge injection of epinephrine).

B. Mutagenicity Study

Dimethyl ether did not induce a genotoxic response in the five *S. typhimurium* strains tested with or without S9-activation.

C. Developmental Toxicity

There are two inhalation developmental toxicity rat studies, both conducted in 1981. One study was conducted in Sprague-Dawley rats at concentrations of 0, 0.125, 0.5, and 2.0% and a second study was conducted in Wistar rats at concentrations of 0, 2.0 and 2.8%.

In the study conducted using Sprague-Dawley rats, at 2.0%, decreased response to tapping on the glass wall of the inhalation chamber was identified by the study authors. This cage-side type evaluation was not well-characterized in the report. The observations in these studies may not have been conducted in a manner consistent with determining a true no observed adverse effect level (NOAEL) for neurotoxic effect in dams. The NOAEL for maternal toxicity is 0.5%.

The developmental toxicity findings are remarkedly similar across both studies. The fetal observations were referred to by different names in the two laboratories. But, both laboratories were referring to skeletal variations. Combining the results of both studies, there is an unequivocal, statistically significant dose-related response for both fetuses and litters at 0.5, 2.0, and 2.8%. The NOAEL for this finding is 0.125%.

The results of the two studies also indicated delays in ossification. The incidence is statistically significant at 2.0% in the first study and at 2.8% in the second study. Non-statistically significant increases in this finding occur at 0.5% in the first study and at 2.0% in the second study.

Taken together, the results of the two developmental toxicity studies are:

- Developmental NOAEL = 0.125% (v/v) equivalent to 2.4 mg/L or 1,250 ppm.
- Developmental LOAEL = 0.5% (v/v) equivalent to 9 mg/L or 5,000 ppm based on an increased incidence of ribs with extra ossification center.
- Maternal NOAEL = 0.5% (v/v) equivalent to 9 mg/L or 5,000 ppm.
- Maternal LOAEL = 2.0% (v/v) equivalent to 37 mg/L or 20,000 ppm based on decreased responsiveness.

The fact that the developmental NOAEL is less than the maternal NOAEL is a possible indication of increased susceptibility. However, the maternal effects were not always well-characterized.

D. Conclusions

Using the submitted studies and its typical procedures, the Agency classified DME as acute inhalation toxicity Category IV, which is the Agency's category of lowest acute toxicity. No treatment-related effects were noted in a 13-week inhalation study. In both the 2-week and the chronic inhalation studies the LOAELs were determined to be 1%. In a developmental toxicity study, exposure at levels of 0.5% (v/v) produced developmental effects (skeletal variations) but maternal toxicity, other than decreased responsiveness, was not noted. DME is not classifiable as to human carcinogenicity. It produces cardiac sensitization in dogs. For several reasons, the Agency has concerns about the doses at which the studies were conducted. DME's flammablity limits in air are 3.4% by volume (lower limit) and 18.0% (upper limit). Several of the studies were conducted with one or more dose levels greater than the lower limit of flammability.

The Agency's limit concentration for inhalation studies is 2 mg/L, which was greatly exceeded in all studies. The limit concentration is a concept used in animal toxicity testing to establish an upper concentration level beyond which testing is not encouraged: Concentrations higher than the limit concentration represent very unrealistic scenarios. Testing above the limit concentration may not provide the appropriate information on adverse effects which could then support a NOAEL for use in risk assessment. It must be possible to differentiate between toxic effects due to the test substance and toxic effects due to other causes such as stress induced by breathing difficulties.

VI. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from groundwater or surfacewater and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

A. Dietary Exposure

1. *Food.* DME is a gas at room temperature. Significant levels of residues from such a volatile gas are unlikely to be present in food or feed items.

2. *Drinking water exposure.* Residues of a volatile gas such as dimethyl ether

are not likely to be present in any significant quantities in surface water. The estimated half-life in a river is 2.1 hours and in a lake 2.7 days. DME is therefore, not expected to be present in drinking water.

B. Other Non-Occupational Exposure

Dimethyl ether is sponsored under the High Production Volume Challenge Program. This is indicative of over 1 million pounds of DME either produced or imported per year.

Dimethyl ether is used as a propellant in various personal care products such as hairsprays, shaving creams, mousses, deodorants, antiperspirants, baby care products, medical/pharmaceutical products and perfumes. Residential uses could also include air fresheners, disinfectants, furniture polishes, adhesives, insulating foams, paints, and insecticides.

In 1990, an article (MRID 45772201) on simulated consumer exposures to DME was published. The report's authors simulated and then measured breathing zone concentrations of DME for typical hair spray exposures, for both domestic and salon conditions. To assure accuracy, repeated measurements were made, thus yielding the range of reported results. Some of the results were expressed as a time-weighted average concentration over 10 minutes (TWA10). TWA10s are calculated by averaging the peak concentration of DME (at initial release) with the lower concentrations that reflect the rapid dispersal of DME throughout the room over the 10 minute time-frame. Table 2 and Table 3 contain domestic simulated exposures to DME. The difference in the measurements is due solely to a closed door (Table 2) and an open door (Table 3). Examination of the data in the tables, indicates that the peak concentration of DME declines substantially from the initial (peak) spray, to the TWA10, to the residual 20-minute concentration whether the door is open or closed.

TABLE 2.—DOMESTIC DME CONCENTRATIONS FROM SIMULATED HAIRSPRAY USES IN A CLOSED ROOM (ALL VALUES EXPRESSED IN PPM)

Peak concentration hairspray user)	Mean 1,310 Maximum 1,577 Minimum 1,043
Peak concentration (nearby child)	Mean 717 Maximum 762 Minimum 672
TWA10 (hairspray user)	Mean 114 Maximum 143 Minimum 82
TWA10 (nearby child)	Mean 89 Maximum 97 Minimum 86
Residual concentration in the breathing zone at 20 minute (hairspray user)	Mean 62 Maximum 78 Minimum 42
Residual concentration in the breathing zone at 20 minute (nearby child)	Mean 56 Maximum 63 Minimum 41

With the door closed there is an order of magnitude reduction from peak concentration to TWA10 concentration, which is then reduced by half to a residual 20 minute concentration.

TABLE 3.—DOMESTIC DME CONCENTRATIONS FROM SIMULATED HAIRSPRAY USES IN A ROOM WITH AN OPEN DOOR (ALL VALUES EXPRESSED IN PPM)

Peak concentration (hairspray user)	Mean 693 Maximum 837 Minimum 549
Peak concentration (nearby child)	Mean 530 Maximum 954 Minimum 105
TWA10 (hairspray user)	Mean 84 Maximum 107 Minimum 67
TWA10 (nearby child)	Mean 68 Maximum 102 Minimum 38

TABLE 3.—DOMESTIC DME CONCENTRATIONS FROM SIMULATED HAIRSPRAY USES IN A ROOM WITH AN OPEN DOOR (ALL VALUES EXPRESSED IN PPM)—Continued

Residual concentration at 20 minutes (hairspray user)	Mean 23 Maximum 41 Minimum 8
Residual concentration at 20 minutes (nearby child)	Mean 24 Maximum 42 Minimum 7

With an open door, the dispersion of the DME occurs so rapidly, that even the peak concentration (Table 3) is less than the peak concentration in Table 2 (door closed). Having an open door and the resultant more rapid dispersion means that DME concentrations are 25% lower.

There is an additional factor that must also be considered in understanding the DME use pattern in the home. The above estimates considered that the user and the nearby child were perfectly still and did not move for 20 minutes. This is an unlikely possibility. It is more likely that the user and the nearby child would move away from the area where the spray occurred within that 20 minute time-frame.

To examine use as an inert ingredient in pesticide products, the Agency examined a scenario likely to yield a higher exposure: Foggers. Release of DME occurs via activation of the fogger, as the propellant releases and fills the enclosed area. The average amount of DME found in a pesticide fogger product is 67.2 grams (g). If the 67.2 grams is suddenly released into a 136 m^3 area, then the concentration in the room equals 67.2 g DME/136m^3 = 0.49 g/m^3 or 490 mg/m^3 at the time of release.

Label directions for foggers indicate that no one is to be present during the application of the pesticide product and for a short period of time afterward. A standardized time-frame for re-entry is 2 hours. The concentration of DME in the room at the end of two hours can be estimated using a decrease of approximately 50% to account for the dispersion of DME from the residence. The 50% rate of decline was based on a study (MRID 45772401) that used a testing chamber with ''ceilings'' that were 11 ft. high. The average measured concentration of DME in the chamber declined by approximately 50% over a period of two hours. The 245 (50% of 490) mg/m^3 used as the starting point in Table 2 is an over-estimate since the testing chambers are usually designed to be airtight. DME would escape from a house much faster through the cracks and crevices around doors and windows.

At the end of two hours, the homeowner re-enters the house, not to stay, but to open doors and windows for venting. Rapid venting occurs immediately as the doors and window are opened. (Labels indicate that venting should occur for at least 30 minutes.) Assuming, (1) that the above 136m^3 area could have one door and three windows, depending on the layout, and (2) every 10 minutes the DME concentration drops 10% due to dispersal, 25% for a door and 10% for a window, then a 65% reduction in DME concentration occurs every 10 minutes. Each line in Table 4 represents 10 minutes. Therefore, the initial concentration of 245 mg/m^3 (Column 1) reduces to 86 mg/m^3 (Column 2). The next 10 minute time-frame (Line 2) begins with 86 mg/m^3 in Column 1.

TABLE 4.—DME CONCENTRATION VS. TIME

Starting Concentration of DME (mg/m^3)	Concentration Minutes Later (mg/m^3)	Total Elapsed Time Since Re-entry (minutes)
245	86	10
86	30	20
30	11	30

VII. Cumulative Effects

Section 408(b)(2)(D)(v) of the 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 DME. Dimethyl ether does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that DME has 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/*.

VIII. Safety Factor for Infants and Children

Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children.

The toxicity database for DME is adequate for the purpose of establishing

this tolerance exemption for use of DME as an inert ingredient (propellant) in a pesticide product. From that toxicity database, the Agency could select a toxicological endpoint to use in the Agency's risk assessment. In selecting an endpoint, EPA matches, as best possible, the time-frames of a potential user's exposure to the time-frames of the toxicity study(ies). Selection of a developmental NOAEL for use in assessing short-term risk appears, at first glance, to be a good match. However, the test animals were confined in the test chambers for 6 hours/day for either 10 or 11 consecutive days, receiving an artificially maintained atmosphere to breathe. The concentrations of DME used in the toxicity studies considered in this final rule are maintained by enclosed test chambers and constant in-flow of DME. Such concentrations cannot be maintained in any building such as greenhouses, apartments, single-family dwellings, or places of business, since any released DME will disperse from the structure via cracks and crevices. Unless, the DME is continually released in that environment, the DME concentration is always decreasing. Therefore, although these studies provide some information concerning potential toxicological hazards of DME, they do not provide useful information for quantitatively assessing the risks from human exposure to DME given the dissimilarity in duration between likely human exposure and the exposure patterns in the studies.

Further, for DME, in the developmental toxicity study, the dose levels used in these inhalation toxicity studies routinely exceeded the limit concentration. It is also noted that dose concentrations in several of the toxicity studies exceed the DME flammable limits and routinely exceed the industrial time-weighted 8-hour day average acceptable exposure limit of 1,000 ppm recommended by DuPont and the American Industrial Hygiene Association. Effects appearing above the limit concentration may not indicate the toxicity of the chemical.

Given the extreme testing conditions in these studies and the effects observed, EPA believes it has adequate data to evaluate the safety of DME. Further, when the hazard testing data is evaluated in light of exposure information, EPA has determined that a safety factor analysis is neither appropriate or needed to assess the risk. For the same reasons a tenfold safety factor is unnecessary.

IX. Determination of Safety for U.S. Population, and Infants and Children

The NOAELs or LOAELs in any of the toxicological studies for DME are significantly higher than any concentration that could be reasonably expected in a home environment given the volatility of DME. The confined, artificially-maintained environment and a 6 hour exposure used in the toxicological studies are not readily comparable to the highly dispersive nature of DME and does not consider the massive reductions in concentration that occur in a 20 to 30 minute time-frame as shown in Tables 2, 3, and 4.

DME is widely used in consumer products that are not regulated by EPA. Simulated consumer exposures for domestic hairspray use are presented in Tables 2 and 3. The magnitude of the EPA-regulated exposures expected from use in a pesticide product is not dissimilar to those of other consumer products. However, the possible number of products containing DME are dissimilar, as well as the use patterns. There is a wide-variety of consumer use patterns, including personal care products, which during use are aimed directly at the user, for example hair spray. Types of pesticide products containing DME are the spray can (which during use is not directed at the individual), and foggers (where the individual is directed to not be present). In most cases, the consumer use patterns and the pesticide use patterns are not likely to overlap. One is unlikely to use a consumer product in a house that is being fogged. One is unlikely to spray paint and apply hairspray at the same time. The activities would usually be separated by time and occur in different rooms.

The exposure estimates presented by the Agency are considered to be over-estimates. It is very likely the DME will disperse more rapidly and/or an individual would remove themselves from the location of the peak concentration.

Given the rapid dispersion of DME from a home via cracks around doors and windows, as well as via open doors and windows, and the likelihood of an exposed individual to move away from the peak concentration area, exposures to DME from use in a pesticide product, or any other product such as hair spray, are very small. Based on the available information on these very small exposures, the volatile nature of DME and its rapid dispersion, the use of dose levels in the toxicological studies which are greater than the limit concentration, toxicity studies that do not readily lend themselves to selection of an appropriate dose and endpoint for such a short duration, and effects that are occurring only at levels greater than the limit concentration, EPA finds that exempting DME, also known as methane, oxybis, (CAS Reg. No. 115–10–6) from the requirement of a tolerance will be safe for the general population including infants and children.

X. Other Considerations

A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect * * *'' EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing DME, also known as methane, oxybis, (CAS Reg. No. 115–10–6) for endocrine effects may be required.

B. Analytical Method(s)

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Existing Tolerances

There is an existing exemption from tolerance for DME when used as a propellant (40 CFR 180.930) in pesticide formulations applied to animals.

D. International Tolerances

The Agency is not aware of any country requiring a tolerance for DME nor have any CODEX Maximum Residue Levels (MRL's) been established for any food crops at this time.

XI. Conclusion

Therefore, an exemption from the requirement for a tolerance is established for DME, also known as methane, oxybis, (CAS Reg. 115–10–6).

XII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to

reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old FFDCA sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2005–0109 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before July 18, 2005.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit XI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP–2005–0109, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

XIII. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR

67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XIV. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 27, 2005.

Betty Shackleford,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180 —[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.910 is amended by adding alphabetically, the following entry.

§ 180.910 Insert ingredients used pre-harvest and post-harvest; Exemptions from the requirement of a tolerance.

* * * * *

Inert ingredient	Limit	Use
* *	* * *	*
Dimethyl ether (methane, oxybis-) (CAS Reg. No. 115–10–06)	.....	Propellant
* *	* * *	*

[FR Doc. 05–9475 Filed 5–17–05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2004–0361; FRL–7711–7]

Red Cabbage Color; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of red cabbage color when used as an inert ingredient (visual pH indicator) in pesticide formulations applied in or on certain various food commodities. Colarome Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of red cabbage color.

DATES: This regulation is effective May 18, 2005. Objections and requests for hearings must be received on or before July 18, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit XIV. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under docket identification (ID) number OPP–2002–0292. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Rame Cromwell, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9068; e-mail address: *cromwell.rame@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in insert appropriate cite to either another