ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2008–0671; FRL–8802–4]

Choline chloride; 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 choline chloride (CAS Reg. No. 67–48–1) applied pre-harvest on all raw agricultural commodities when applied/used as a solvent. Loveland Products, Inc., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of choline chloride.

DATES: This regulation is effective January 6, 2010. Objections and requests for hearings must be received on or before March 8, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2008–0671. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Deirdre Sunderland, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 603–0851; e-mail address: *sunderland.deirdre@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 code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 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 Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, 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. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2008–0671 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 March 8, 2010.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA–HQ–OPP–2008–0671, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of December 3, 2008 (73 FR 73648) (FRL–8391–3), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 8E7387) by Loveland Products, Inc., P.O. Box 1286, Greeley, CO 80632–1286. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of choline chloride when used as an inert ingredient in pesticide formulations applied pre-harvest. That notice included a summary of the petition prepared by the petitioner. There were no comments received in response to the notice of filing.

Section 408(b)(2)(A)(i) of 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 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 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 ploymers 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. Toxicological Profile

Consistent with section 408(b)(2)(D) of 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 caused by choline chloride are discussed in this unit. The following provides a brief summary of the risk assessment and conclusions from the Agency's review of choline chloride. The Agency's full decision document for this action is available in the Agency's electronic docket (regulations.gov) under the docket number EPA–HQ–OPP–2008–0671.

Choline chloride is a quaternary ammonium salt which dissociates in water resulting in a positively charged quaternary hydroxyl alkylammonium ion and a negatively charged chloride ion. Choline is an essential component of the human diet and acts as a precursor to acetylcholine, phospholipids, and the methyl donor betaine. It is important for the structural integrity of cell membranes, cholinergic neurotransmission, transmembrane signaling, methyl metabolism, and lipid and cholesterol transport and metabolism.

Choline was officially made an ''essential nutrient'' in 1998 and adequate intake (AI) levels were established (women-425 milligram/day (mg/day), pregnant women-450 mg/day, men and lactating women-550 mg/day). The Daily Upper Intake Level for choline is 3.5 grams for adults. Research indicates that many individuals are not getting enough choline, with daily intake levels far below the AI.

Chloride is a binary compound of chlorine; a salt of hydrochloric acid. Chloride is the major extracellular anion and contributes to many body functions including the maintenance of osmotic pressure, acid-base balance, muscular activity, and the movement of water between fluid compartments. The World Health Organization has performed two assessments which determined that from a toxicological point of view, there were no concerns for the chloride ion. It was considered to be naturally-occurring and a normal participant of animal and human metabolism.

Choline chloride has demonstrated a low acute oral toxicity with LD_{50} values for rats ranging from 3,150 to ≥ 6,000 milligram/kilogram (mg/kg) and LD_{50} for mice in the range of 3,900 to 6,000 mg/kg. Although appropriate animal studies are lacking for acute dermal toxicity, an *in vitro* percutaneous absorption study performed under occluded and unoccluded conditions showed that choline chloride is expected to have a low potential for percutaneous absorption. Acceptable acute inhalation studies are not available. Studies conducted in the early 1960's showed only slight transient irritation of the skin and eye.

Repeat dose animal studies on choline chloride are limited. One study in mice evaluated the impact of 200 mg/kg/day choline chloride given orally or intranasally for 28 days. No adverse effects were observed with regards to body weight, food and water consumption, hematology, clinical biochemistry, or histopathology of various organs (lung, heart, liver, spleen, and kidney). Results from intranasal exposure to choline chloride were comparable with their respective controls and to other treatment groups. The no adverse effects are observed (NOAEL) for oral and intranasally administered choline chloride is ≥ 200 mg/kg/day.

A 72–week feeding study in rats administered 500 mg/kg/day of choline chloride and observed the animals for 30 weeks post exposure. There were no significant difference between the control and treated group in relation to body weights, relative liver weight, survival rates, and the number of neoplastic liver nodules, hepatocellular carcinomas, lung tumors, leukemia, or other tumors. This study resulted in a NOAEL of 500 mg/kg/day (the highest dose tested).

Choline is a precursor to the vital neurotransmitter acetylcholine. Studies show that choline has beneficial effects on the nervous system and memory. Choline is necessary to promote proper development in the fetus and infant and prevent cognitive problems. Choline chloride is not expected to cause neurotoxicity and it is not a known endocrine disruptor nor are its metabolites related to any class of known endocrine disruptors. Based on the results of the *in vitro* and *in vivo* studies the Agency concluded that choline chloride is not expected to be carcinogenic or mutagenic.

Since the 1930's choline chloride has been used as a widespread nutrient in animal feed without adverse effects reported on fertility or teratogenicity. The Food and Drug Administration (FDA) requires choline be added to non-milk based infant formulas at a minimum concentration of 7 mg for every 100 kilocalories (21 CFR 107.100). Although one study did show developmental effects, they were only seen at very high doses (≥4,160 mg/kg/day) and only in the presence of maternal toxicity. There were no observed adverse effects for both mothers and pups exposed to 1,250 mg/kg/day. Based on this information the Agency concluded that choline chloride, when used as an inert ingredient, will not cause reproductive or developmental toxicity and therefore, does not anticipate an increased risk to infants and children.

V. Aggregate Exposures

In examining aggregate exposure, section 408 of 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 ground water or surface water 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 clearly 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.

Exposure from the use of choline chloride is expected through the oral route via food and drinking water. Exposure via the dermal route may occur for those individuals applying the product both occupationally and residentially. Due to the rapid degradation of the chemical and the natural presence of choline and chloride in the environment, exposure from the use of choline chloride as an inert ingredient in pesticide products is not expected to increase the aggregate exposure to all subpopulation including infants and children and therefore a quantitative exposure assessment has not been performed.

VI. Cumulative Effects

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 choline chloride and any other substances, and these chemicals 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 these chemicals 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/*.

VII. Additional Safety Factor for the Protection of Infants and Children.

Section 408 of 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. EPA concluded that the FQPA safety factor for choline chloride should be reduced to 1X.

The database for choline chloride is adequate to make a determination of safety for infants and children. Choline is a natural component of a variety of commonly consumed foods. It has been added as a supplement to infant formula in the United States for decades. In addition to dietary consumption of choline and chloride, choline is made endogenously in the human body. Choline is a precursor to the vital neurotransmitter acetylcholine. Studies show that choline has beneficial effects on the nervous system and memory. Choline is necessary to promote proper development in the fetus and infant and prevent cognitive problems. Choline chloride is not expected to cause neurotoxicity.

Chloride is also important for many biological functions. It helps to maintain the fluid balance of cells, proper blood volume, blood pressure, and the pH of body fluids. The World Health Organization has performed two assessments which determined that from a toxicological point of view, there were no concerns for the chloride ion. It was considered to be naturally-occurring and a normal participant of animal and human metabolism.

Choline chloride has been used as a widespread nutrient in animal feed since the 1930's without adverse effects reported on fertility or teratogenicity. Although one study in mice did show developmental effects, they were only seen at very high doses (≥4,160 mg/kg/day) and only in the presence of maternal toxicity. There were no observed adverse effects for both mothers and pups exposed to 1,250 mg/kg/day.

Exposure to choline chloride is not expected to significantly increase the pre-existing levels found in commonly eaten foods. Due to the negligible anticipated crop residues and subsequent exposure, the low toxicity of the chemical and its metabolites, the bodies need for choline from a dietary source, and the beneficial role choline plays in fetal development and memory; the safety factor has been reduced to 1 X.

VIII. Determination of Safety for U.S. Population

In addition to its low toxicity, exposure to choline chloride will be limited. The expected exposure pathway is via the oral and the dermal routes. Humans are currently exposed to choline and chloride on a daily basis through commonly eaten foods (both naturally occurring and when added as a nutrient) and through the bodies natural ability to synthesize the nutrient. It is unlikely that the exposure from choline chloride, when used as an inert ingredient applied pre-harvest to food commodities, will significantly increase the natural concentration of choline and chloride in foods. Choline and chloride are also found naturally in the environment. Choline chloride is readily biodegradable and because of its high water solubility it is expected that most of the inert will be washed from the plant prior to consumption. Once in water, its preferred media, it will be broken into a quaternary hydroxyl alkylammonium ion and a chloride ion.

Taking into consideration all available information on choline chloride, it has been determined that there is a reasonable certainty that no harm to any population subgroup, including infants and children, will result from aggregate exposure to this chemical. Therefore, the exemption from the requirement of a tolerance for residues of choline chloride (CAS Reg. No. 67–48–1), when used as an inert ingredient in pre-harvest applications, under 40 CFR 180.920 can be considered safe under section 408(q) of the FFDCA.

IX. Other Considerations

A. 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.

B. International Tolerances

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

X. Conclusions

Therefore, a tolerance exemption is established for choline chloride (CAS Reg. No. 67–48–1) when used as inert ingredient in pesticide formulations applied to growing crops only.

XI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of 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 final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

XII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: December 24, 2009.

Lois Rossi,

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. In §180.920, the table is amended by adding alphabetically the following inert ingredients:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

Inert ingredients	Limits	Uses
* * *	*	*
Choline chloride (CAS Reg. No. 67–48–1)	---------- ------	As a solvent
* * *	*	*

[FR Doc. E9–31280 Filed 1–5–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0610; FRL–8802–5]

Dibenzylidene Sorbitol; 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 dibenzylidene sorbitol (CAS Reg. No. 32647–67–9) under 40 CFR 180.920 when used as the inert ingredient in pesticdes formulations applied in or on growing crops. Dow Agrosciences LLC submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of dibenzylidene sorbitol.

DATES: This regulation is effective January 6, 2010. Objections and requests for hearings must be received on or before March 8, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0610. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (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 in the electronic docket at *http://www.regulations.gov*, or, if only