■ 3. In appendix C to part 4022, Rate Set 230, as set forth below, is added to the table.

Appendix C to Part 4022—Lump Sum Interest Rates For Private-Sector Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*	*	
230	12–1–12	1–1–13	0.75	4.00	4.00	4.00	7	8

Issued in Washington, DC, on this 7th day of November 2012.

Laricke Blanchard,

Deputy Director for Policy, Pension Benefit Guaranty Corporation.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0951; FRL–9361–3]

Xylenesulfonic Acid, Sodium Salt; 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 xylenesulfonic acid, sodium salt (also known as sodium xylene sulfonate) (CAS Reg. No. 1300–72–7) when used as an inert ingredient in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, diary processing equipment, and food processing equipment and utensils at 500 parts per million (ppm) utensils. The firm Exponent on behalf of Ecolab Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of sodium xylene sulfonate.

DATES: This regulation is effective November 16, 2012. Objections and requests for hearings must be received on or before January 15, 2013, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2011–0951, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Mark Dow, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–5533; email address: *dow.mark@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 get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 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. 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–2011–0951 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before January 15, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2011–0951, by one of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Petition for Exemption

In the **Federal Register** of March 14, 2012 (77 FR 15012) (FRL–9335–9), EPA issued a notice pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 1E7936) by Exponent on behalf of Ecolab Inc. (370 N. Wabasha Street, St. Paul, MN 55102). The petition requested that 40 CFR 180.940(a) be amended by an exemption from the requirement of a tolerance for residues of xylene sulfonic acid, sodium salt (also known as sodium xylene sulfonate; CAS no. 1300–72–7) when used as an inert ingredient as an antimicrobial agent in pesticide formulations applied to ''food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils'' at a maximum of 500 ppm. That notice referenced a summary of the petition prepared by Exponent on behalf of Ecolab Inc. (370 N. Wabasha Street, St. Paul, MN 55102), the petitioner, which is available in the docket, *http://www.regulations.gov.* Sodium xylene sulfonate is currently approved for use in pesticide formulations applied to growing crops and animals under the existing exemptions from the requirement of a tolerance given at 40 CFR 180.920 and 40 CFR 180.930. Sodium xylene sulfonate is currently approved as an inert ingredient under 40 CFR 180.940(c) for use in food contact surface sanitizing solutions applied to food processing equipment and utensils at an end-use concentration not to exceed 62 ppm. The current petition seeks to expand the existing use of sodium xylene sulfonate to include use on food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils. Hence, the petition requests the establishment of an exemption covering this new use in 40 CFR 180.940(a). There were no comments received in response to the notice of filing.

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. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(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 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.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for sodium xylene sulfonate including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with sodium xylene sulfonate follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies 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. Specific information on the studies received and the nature of the adverse effects caused by sodium xylene sulfonate as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Sodium xylene sulfonate has low acute toxicity by the oral, dermal and inhalation route of exposure. Sodium xylene sulfonate is a slight skin and mild eye irritant. Based upon information regarding sodium toluene sulfonate, sodium xylene sulfonate is negative for dermal sensitization. Several subchronic studies via the oral route of exposure are available in the database. In two 14-day toxicity studies in mice and rats, no significant treatment related toxicity was observed at doses up to 4% in the diet (approximately 4,000 milligrams/kilogram/day (mg/kg/day)) in mice. In rats, there were some mortalities which were not observed in a dose-related manner and losses of body weight that were probably due to palatability of the test article. In a repeat toxicity study in rats, mortality was not observed at doses up to 4% in the diet. A 90-day subchronic toxicity study was conducted in Wistar rats with doses of sodium xylene sulfonate up to 5% in

the diet. A decreased in relative spleen weight of females, along with some clinical chemistry and hematology changes were observed at the highest dose (3,454 mg/kg/day). In a separate 90-day toxicity study in rats and mice, no treatment related effects were observed in mice and rats given sodium xylene sulfonate in the diet at 2% (approximately 2,439 and 2,467 mg/kg/day in mice and rats, respectively). Dermal toxicity studies for 17 days and 90 days duration were conducted in mice and rats. No systemic toxicity was observed in mice and rats exposed dermally to sodium xylene sulfonate at doses up to 1,620 and 500 mg/kg/day in mice and rats, respectively. The results of a 2-year dermal toxicity study showed no evidence of skin neoplasms or any other neoplasms at doses up to 727 and 240 mg/kg/day in mice and rats, respectively. Additionally, the Agency used a qualitative structure activity relationship (SAR) database, DEREK11, to determine if there were structural alerts suggestive of carcinogenicity. No structural alerts for carcinogenicity were identified.

Sodium xylene sulfonate was tested for its mutagenic potential in various *in vivo* and *in vitro* genotoxicity assays. It gave a negative response in a mouse lymphoma assay, the Ames assay, Sister Chromatid Exchange assay, (positive at cytotoxic concentrations only), a Chromosome Aberration Test and three mouse micronucleus assays. Therefore, sodium xylene sulfonate is not likely to be mutagenic.

There are no reproductive toxicity studies for sodium xylene sulfonate. However, the Organisation for Economic Co-operation and Development (OECD) Screening Information Dataset (SIDS) Assessment included reviews of a 91-day oral rat feeding study with sodium cumene sulfonate, a 90-day feeding study with sodium xylene sulfonate (mice and rats), and the 2-year dermal studies with sodium xylene sulfonate (mice and rats) which included examination of the reproductive organs of both sexes. There was no evidence from these studies to suggest that sodium xylene sulfonate would have an adverse effect on reproductive organs by either the oral or dermal route. No developmental toxicity studies in rats and rabbits are available in the sodium xylene sulfonate database. However, a developmental study with the rat is available for a surrogate chemical, calcium xylene sulfonate. In this study the NOAEL for maternal and fetal toxicity was the highest dose tested; 3,000 mg/kg/day which correspond to 936 mg/kg bw/day. Based on the calcium xylene sulfonate OECD Guideline study, there is no evidence to consider these materials as being developmental toxicants. There is no evidence in the sodium xylene sulfonate database that sodium xylene sulfonate is an immunotoxin.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

No endpoint of concern following a single dose was identified in the available database. The Agency identified a NOAEL of 763 mg/kg bw/day for systemic toxicity, which was selected from an oral subchronic study. Effects observed in this study were a decrease in spleen weight in females along with some clinical chemistry and hematology changes at the LOAEL of 3,454 mg/kg bw/day. No adverse effects were reported in males. This study was used for chronic dietary exposure assessment. An uncertainty factor of 100X is applied (10X for interspecies extrapolation and 10X for intraspecies variability). Based on the physicochemical data and lack of systemic toxicity in the available dermal toxicity studies, EPA concluded that there is no need to conduct quantitative dermal risk exposure assessment. For several reasons, no additional uncertainty factor is necessary for the use of subchronic study data for chronic exposure assessment. First there was a wide dose spread between the toxic effects seen at the LOAEL of 3,454 mg/kg/day and the NOAEL of 763 mg/kg/day. Second, the changes observed in clinical chemistry and hematological parameters were small in magnitude and no effects on organs were observed in the study. Therefore, the changes observed were not considered toxicologically significant. Finally, the NOAEL in a separate 90-day study in rats was 2,467 mg/kg/day indicating the lower NOAEL value in the selected study is an artifact of dose selection. Therefore, EPA concluded that there is no need to add an additional uncertainty factor for use of short-term study for long-term exposure assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to sodium xylene sulfonate, EPA considered exposure under the proposed exemption from the requirement of a tolerance (40 CFR 180.940(a)) and as an inert ingredient used in pesticide formulations applied to growing crops and animals under the existing exemptions from the requirement of a tolerance given at 40 CFR 180.920 and 40 CFR 180.930. EPA assessed dietary exposures from sodium xylene sulfonate in food as follows:

In the absence of actual dietary exposure data resulting from this proposed use the EPA has utilized a conservative, health-protective method of estimating dietary intake that is based upon conservative assumptions related to the amount of residues that can be transferred to foods as a result of the proposed use of sodium xylene sulfonates in food contact sanitizing pesticide products. This same methodology has been utilized by EPA in estimating dietary exposures to antimicrobial pesticides used in food-handling settings. The Agency believes the assumptions used to estimate chronic dietary exposures lead to an extremely conservative assessment of chronic dietary risk due to a series of compounded conservatisms as described in the unit. First, when a surface is treated with a disinfectant, a quantity of the disinfectant remains on the surface (Residual Solution). In the absence of any other data, EPA has used an estimated worst-case concentration of 1 mg of solution per square centimeter (cm^2) of treated surface area for this quantity. Second, the conservatism of this methodology is compounded by EPA's decision to assume a worst case scenario that all food that an individual consumes will

come into contact with 4,000 cm^2 of sanitized non-porous food-contact surfaces. This contact area represents all the surface area from silverware, china, and glass used by a person who regularly eats three meals per day at an institutional or public facility. The surface area of counter tops that comes in contact with food is expected to be smaller than the surface area for food utensils. As a conservative estimate, EPA assumed that 2,000 cm^2 of treated counter top surface area, comes into contact with an individual's food per day. Third, EPA assumes that 100% of the material present on food contact surfaces will migrate to food. A complete description of the approach used to assess dietary exposures resulting from food contact sanitizing solution uses of sodium xylene sulfonates can be found at *http://www.regulations.gov* in document Decision Document for Petition Number 1E7936, pp. 16 of 30 in docket ID number EPA–HQ–OPP–2011–0951.

In conducting the acute and chronic dietary exposure assessments for sodium xylene sulfonate, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, no residue data are available for sodium xylene sulfonate. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure tolerance for a given commodity from a list of high-use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled ''Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts.'' (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

In the dietary exposure assessment, the Agency assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient.

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms.

First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentration of active ingredient in agricultural products is generally at least 50% of the product and often can be much higher. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient.

Second, the conservatism of this methodology is compounded by EPA's decision to assume that, for each commodity, the active ingredient which will serve as a guide to the potential level of inert ingredient residues is the active ingredient with the highest tolerance level. This assumption overstates residue values because it would be highly unlikely, given the high number of inert ingredients, that a single inert ingredient or class of ingredients would be present at the level of the active ingredient in the highest tolerance for every commodity.

Finally, a third compounding conservatism is EPA's assumption that all foods contain the inert ingredient at the highest tolerance level. In other words, EPA assumed 100% of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient.

In summary, EPA chose a very conservative method for estimating what level of inert residue could be on food, then used this methodology to choose the highest possible residue that could be found on food and assumed that all food contained this residue. No consideration was given to potential degradation between harvest and consumption even though monitoring data shows that tolerance level residues are typically one to two orders of magnitude higher than actual residues of magnitude higher than actual residues in food when distributed in commerce. Accordingly, although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for sodium xylene sulfonate, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for sodium xylene sulfonate. These values were directly entered into the dietary exposure model. Further details of this drinking water analysis can be found at *http://www.regulations.gov* in document ''Decision Document for Petition Number 1E7936'', pp. 16 of 30 in docket ID number EPA–HQ–OPP–2011–0951.

The proposed use of sodium xylene sulfonate will not result in its presence in surface water or ground water and therefore not contribute to dietary exposure.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Sodium xylene sulfonate is not used as an inert ingredient in pesticide products that are registered for specific uses that may result in either indoor and outdoor residential exposures. However, sodium xylene sulfonate is used as a component of personal care products. The OECD SIDS Assessment estimated highest human exposures resulting from personal care product use. The exposure estimates ranged from 0.02–0.14 mg/kg/day for shampoos and hair conditioners to 0.11–0.17 mg/kg/day for liquid face and hand soaps. Exposure estimates for cleaning product use and residuals on clothing range from 0.01–0.08 mg/kg/day. All exposure evaluations included conservative (protective) input assumptions (e.g., all modeled human exposures are conservative due to the use of a default assumption of 100% absorption). However, the physicochemical data and available toxicological data suggest that dermal absorption is likely to be minimal. Based on the lack of concern for dermal toxicity and the low estimates of residential exposure, a quantitative residential risk assessment was not performed.

4. *Cumulative effects from substances with a common mechanism of toxicity.* 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.''

EPA has not found sodium xylene sulfonate to share a common mechanism of toxicity with any other substances, and sodium xylene sulfonate does not appear to produce a toxic metabolite produced by other substances. However, there are other chemicals belonging to the xylene sulfonate class of chemicals that may have a similar toxicity profile but these chemicals will be used as an alternative to sodium xylene sulfonate. Therefore, a cumulative risk assessment was not performed. Furthermore, the cPAD for pesticidal uses occupies only 7% of the cPAD for the general population and any potential increase in exposure to this class of chemicals will still be below any levels of concern. For the purposes of this tolerance action, therefore, EPA has assumed that sodium xylene sulfonate does not 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 EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) 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 based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There are no reproductive toxicity studies reported for sodium xylene sulfonate. However, no effects on reproductive organs were observed at very high doses in number of studies such as a 91-day oral rat feeding study with sodium cumene sulfonate, the 90-day feeding study with sodium xylene sulfonate, and the 2-year dermal studies with sodium xylene sulfonate. Based on the above evidence, EPA concluded that sodium xylene sulfonate is not likely to be reproductive toxicant. This conclusion is in agreement with the OECD conclusion that there is no evidence to suggest that sodium xylene sulfonate would have an adverse effect on reproductive organs.

In a developmental toxicity study in rats with calcium xylene sulfonate, no maternal or developmental effects were observed at doses of 3,000 mg/kg/day (equal to 936 mg/kg/day corrected for purity of test material).

There is no evidence of prenatal or postnatal sensitivity as a result of exposure to sodium xylene sulfonate.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to [1X]. That decision is based on the following findings:

i. Available studies included several 90-day toxicity studies via oral and dermal routes, chronic studies, mutagenicity battery, a developmental study in rats and metabolism studies. These studies provide an adequate characterization of sodium xylene sulfonate toxicity.

ii. There is no indication that sodium xylene sulfonate is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. No reproductive toxicity study or developmental toxicity study are available for sodium xylene sulfonate. However, the concern for increased susceptibility of infants and children exposure to sodium xylene sulfonate are low because no effects on reproductive parameters were observed in various oral toxicity studies and the developmental toxicity in rats for a surrogate chemical show lack of systemic toxicity at doses up to 936 mg/kg/day (mentioned under pre and post natal susceptibility).

iv. No evidence of immunotoxicity was observed in the database except slightly decreased in spleen weight was observed at the LOAEL of 3,454 mg/kg bw/day. There are no concerns for immunotoxicity and an immunotoxicity study is not required because the slight decreased in spleen weights were observed at high doses without any evidence of histopathological findings.

v. No additional uncertainty factor is needed for the use of subchronic study data for chronic exposure assessment. The rational for this decision is provided in Unit IV.B.

vi. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100% CT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to sodium xylene sulfonate in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by sodium xylene sulfonate.

E. Aggregate Risks and Determination of Safety

Determination of safety section. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, sodium xylene sulfonate is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to sodium xylene sulfonate from food and water including those uses for which tolerance exemptions under 40 CFR (180. 910, and 40 CFR 180.930 exist) will utilize 7% of the cPAD for the U.S. population and 26% of the cPAD for children 1–2 years old, the population subgroup receiving the greatest exposure. There are no residential uses for sodium xylene sulfonate.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short-term adverse effect was identified; however, sodium xylene sulfonate is not currently used as an inert ingredient in pesticide products that are registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective

cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for sodium xylene sulfonate.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, sodium xylene sulfonate is not currently used as an inert ingredient in pesticide products that are registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for sodium xylene sulfonate.

5. *Aggregate cancer risk for U.S. population.* Based upon no evidence of carcinogenicity in two adequate rodent carcinogenicity studies via the dermal route of exposure, negative response for mutagenicity in a battery of genotoxicity tests, and lack of any structural alerts for carcinogenicity, sodium xylene sulfonate is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to sodium xylene sulfonate residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of xylene sulfonic acid, sodium salt in or on any food commodities. EPA is establishing a limitation on the amount of xylene sulfonic acid, sodium salt that may be used in pesticide formulations. That limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide for sale or distribution for which the final end use concentration of xylene sulfonic acid, sodium salt in antimicrobial, food contact surface sanitizing solutions would exceed 500 ppm.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nation Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for sodium xylene sulfonate.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940(a) for xylenesulfonic acid, sodium salt (CAS Reg. No. 1300–72–7) when used as an inert ingredient in antimicrobial formulations in pesticide formulations applied to food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils at a maximum of 500 parts per million of final solution. Additionally the exemption from the requirement of a tolerance for xylenesulfonic acid under 40 CFR 180.940(c), can be removed as the establishment of a broader exemption from the requirement of a tolerance for xylenesulfonic acid under 180.940(a) obviates the need for 40 CFR 180.940(c) tolerance exemption.

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCA section 408(d) 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 FFDCA section 408(d), such as the tolerance 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 FFDCA section 408(n)(4). 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) (Pub. L. 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).

VIII. 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: November 1, 2012.

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. Section 180.940 is amended by adding the entry ''Xylenesulfonic acid, sodium salt'' to the table in paragraph (a) and removing the entry for ''Xylenesulfonic acid'' in the table in paragraph (c) to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

(a) * * *

Pesticide chemical	CAS Reg. No.	Limits
* * * * * * *		
Xylenesulfonic acid, sodium salt.	1300–72–7	When ready for use, the end-use concentration is not to exceed 500 ppm.

* * * * *

[FR Doc. 2012–27406 Filed 11–15–12; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–1029; FRL–9368–2]

1,4-Dimethylnaphthalene; Amendment to an Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the existing exemption from the requirement of a tolerance for residues of the plant growth regulator, 1,4-dimethylnaphthalene (1,4-DMN) by expanding the current exemption to include all sprouting root and tuber vegetables (EPA Crop Group 01) and all bulb vegetables (EPA Crop Group 03). On behalf of D-I-1-4, Inc., a division of 1,4Group, Inc., Technology Sciences Group, Inc. (TSG) submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting that EPA amend the existing exemption from the requirement of a tolerance for 1,4-DMN. This regulation eliminates the need to establish a maximum permissible level for residues of 1,4-DMN under the FFDCA.

DATES: This regulation is effective November 16, 2012. Objections and requests for hearings must be received on or before January 15, 2013, 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: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2011–1029, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Colin G. Walsh, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–0298; email address: *walsh.colin@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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 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. 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–2011–1029 in the subject line on