

approval of a modified method using the alternative kit.

B. Revised Methods

In the April 6, 2004, proposal, EPA proposed changes to approved analytical methods for use in Clean Water Act and Safe Drinking Water Act programs. The proposed changes included methods that employ new technologies and updated versions of previously approved methods. Among these changes, EPA proposed to approve a number of ASTM International methods, including ASTM Method D6888-03 for determining available cyanide in wastewater and drinking water, ASTM Method D5673-02 for determining various metals in wastewater, and ASTM Method D4658-92 for determining sulfide in wastewater. Since publication of the proposal, EPA has received revised versions of these three methods and has added them to the docket for public comment: (1) D6888-04 Standard Test Method for Available Cyanide with Ligand Displacement and Flow Injection Analysis (FIA) Utilizing Gas Diffusion Separation and Amperometric Detection (an update of proposed version: D6888-03); (2) D5673-03 Standard Test Method for Elements in Water by Inductively Coupled Plasma—Mass Spectrometry (an update of proposed version: D5673-02); and (3) D4658-03 Standard Test Method for Sulfide Ion in Water (and update of proposed version: D4658-92(1996)). Method D6888-04 contains a new on-line sulfide removal procedure, and Methods D5673-03 and D4658-03 have added standardized quality control requirements and criteria. The methods added to the Docket represent refinements to the proposed versions, and are not significant variations of those versions. EPA may promulgate some or all of these revised versions in a final rule, and requests comment on each. These methods are included in the docket at OW-2003-0070-0348, 0349, 0350, respectively, and may be ordered from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959, United States, or at <http://www.astm.org>.

In the April 6, 2004 proposal, EPA proposed a method for the measurement of Radium-226 and Radium-228 by Gamma Spectroscopy in drinking water. This method has been modified in several ways and EPA seeks comment on these modifications. The changes to the method include the following: correction of minor typographical errors, minor editorial changes such as the addition of chemical abstract numbers for Radium-226 and Radium-228; the addition of a description of the

dangers regarding the use of diethyl ether; minor changes to the equations for activity, detection limit, and uncertainty made as a result of public comment; minor changes to the QC section of the method; the addition of a description of "mixed wastes" (*i.e.*, waste that contains both hazardous waste and radioactive waste); and the addition of a reference to ASTM added to describe Type 2 Reagent Water.

In the April 6, 2004 proposal, EPA concluded that the proposed rule would not have a significant economic impact on a substantial number of small entities (69 FR 18188). Adoption of the refinement to the three methods for which EPA is requesting comment today would not change the Agency's decision to certify the proposal under the Regulatory Flexibility Act. In addition, as explained above, Methods D6888-04, D5673-03 and D4658-03, like the earlier proposed versions of these methods, represent methods from voluntary consensus standards bodies. Section 12(d) of the National Technology Transfer and Advancement Act of 1995 directs EPA to use voluntary standards in its regulatory activities as discussed in more detail in the proposal at 69 FR 18189-18190.

Dated: February 9, 2005.

Benjamin H. Grumbles,

Assistant Administrator, Office of Water.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2004-0413; FRL-7691-9]

Lignosulfonates; Exemptions from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Agency is proposing to establish 44 exemptions from the requirement of a tolerance for residues of various lignosulfonate chemicals in or on raw agricultural commodities when used as inert ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest, or to animals under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). This regulation eliminates the need to establish a maximum permissible level for residues of these lignosulfonate chemicals.

DATES: Comments, identified by docket identification (ID) number OPP-2004-0413, must be received on or before April 18, 2005.

ADDRESSES: Submit your comments, identified by docket ID number OPP-2004-0413, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov/>. Follow the on-line instructions for submitting comments.

- *Agency Website:* <http://www.epa.gov/edocket/>. EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.

- *E-mail:* Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID Number OPP-2004-0413.

- *Mail:* Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID Number OPP-2004-0413.

- *Hand delivery:* Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP-2004-0413. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number OPP-2004-0413. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.epa.gov/edocket/>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, regulations.gov, or e-mail. The EPA EDOCKET and the regulations.gov websites are "anonymous access" systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through EDOCKET or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is

placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit EDOCKET on-line or see the **Federal Register** of May 31, 2002 (67 FR 38102) (FRL-7181-7).

Docket: 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: Princess Campbell, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8033; e-mail address: campbell.princess@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 and Other Related Information?

In addition to using EDOCKET (<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 on E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.

C. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through EDOCKET, [regulations.gov](http://www.regulations.gov), or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the rulemaking by docket ID number and other identifying information (subject heading, **Federal Register** date, and page number).
- ii. Follow directions. The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at

your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns, and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

The Agency is proposing to establish 44 tolerance exemptions for various lignosulfonate chemicals. Currently, there are seven tolerance exemptions for lignosulfonate chemicals. In 40 CFR 180.910 and 180.930, the exemption reads: Lignosulfonate, ammonium, calcium, magnesium, potassium, sodium, and zinc salts. The Agency intends to remove this single exemption, and split the exemption into separate chemical entries. There are also in 40 CFR 180.910 and 930, exemptions for oxidized pine lignin, sodium salt with a limitation of 2% in the formulation. As part of the proposed actions, the limitation will be removed. The exemptions for pine lignin in 40 CFR 180.910 and 180.930 will be revised to include the Chemical Abstracts Service Registry Number (CAS No.) and a different naming convention. In 40 CFR 180.910 the exemption for ethoxylated lignosulfonic acid, sodium salt will be revised in a similar manner.

In part, this action is based on two pesticide petitions (PP 6E4673 and 6E4674) from LignoTech USA Inc., 100 Hwy. 51 South, Rothschild, WI 54474. LignoTech requested exemptions from the requirement of a tolerance for sulfite liquors and cooking liquors, spent, oxidized; and lignosulfonic acid, sodium salt, oxidized, when used as inert ingredients in pesticide formulations. The petitioner requested that 40 CFR 180.1001(c) and (e) (newly redesignated as 180.910 and 180.930) be amended by establishing these exemptions from the requirement of a tolerance.

EPA on its own initiative, under section 408(e) of FFDCFA, 21 U.S.C. 346a(e), is proposing to amend several existing tolerance exemptions and to establish several new tolerance exemptions for various lignosulfonate chemicals on raw agricultural commodities when used in pesticide formulations as inert ingredients (surfactants or related adjuvants to surfactants) applied to growing crops, or to raw agricultural commodities after harvest and when applied to animals.

The 22 lignosulfonate chemicals, (a total of 44 exemptions), that the Agency is proposing to exempt from the requirement of a tolerance are listed in the Table 1 of this unit.

TABLE 1.—LIGNIN AND LIGNOSULFONATE CHEMICALS PROPOSED FOR TOLERANCE EXEMPTION

Chemical	Chemical formula	CAS No.
Lignosulfonic acid	C ₂₁₃ H ₂₄₆ O ₈₈ S ₆₄	8062-15-5
Lignosulfonic acid, ammonium salt	C ₂₁₃ H ₂₅₈ N ₄ O ₈₈ S ₄	8061-53-8
Lignosulfonic acid, calcium salt	C ₂₁₃ H ₂₄₂ Ca ₂ O ₈₈ S ₄	8061-52-7
Lignosulfonic acid, magnesium salt	C ₂₁₃ H ₂₄₂ Mg ₂ O ₈₈ S ₄	8061-54-9
Lignosulfonic acid, sodium salt	C ₂₁₃ H ₂₄₂ Na ₄ O ₈₈ S ₄	8061-51-6
Lignosulfonic acid, potassium salt	C ₂₁₃ H ₂₄₂ K ₄ O ₈₈ S ₄	37314-65-1
Lignosulfonic acid, zinc salt	C ₂₁₃ H ₂₄₂ O ₈₈ S ₄ Zn ₂	57866-49-6
Lignosulfonic acid, ammonium sodium salt		166798-73-8
Lignosulfonic acid, ammonium magnesium salt		123175-37-1
Lignosulfonic acid, ammonium calcium salt		12710-04-2
Lignosulfonic acid, calcium magnesium salt		55598-86-2
Lignosulfonic acid, calcium sodium salt		37325-33-0
Lignosulfonic acid, sodium salt sulfomethylated	C ₂₁₄ H ₂₄₂ Na ₆ O ₉₄ S ₆	68512-34-5
Lignin alkali reaction products with disodium sulfite and formaldehyde	C ₂₁₃ H ₂₄₈ Na ₂ O ₈₃ S ₂	105859-97-0
Lignin alkali reaction products with formaldehyde and sodium bisulfite	C ₂₁₃ H ₂₄₈ Na ₂ O ₈₃ S ₂	68512-35-6
Ethoxylated lignosulfonic acid, sodium salt	C ₂₁₇ H ₂₅₀ Na ₄ O ₉₀ S ₄	68611-14-3
Lignin, alkali, oxidized, sodium salt	C ₂₁₃ H ₂₃₇ Na ₅ O ₈₁	68201-23-0
Lignin		9005-53-2
Lignin, alkali	C ₂₁₃ H ₂₄₅ Na ₆ O ₇₆	8068-05-1
Lignosulfonic acid, sodium salt, polymer with HCHO and phenol	C ₂₂₉ H ₂₅₆ Na ₃ O ₉₀ S ₄	37207-89-9
Sulfite liquors and cooking liquid, spent, oxidized	C ₂₂₅ H ₂₅₃ Ca ₃ NaO ₁₁₃ S ₇	68514-09-0
Lignosulfonic acid, sodium salt oxidized	C ₂₁₂ H ₂₃₀ Na ₄ O ₈₈ S ₄	68855-41-4

B. What is the Agency's Authority for Taking this Action?

This proposed rule is issued under section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170). Section 408(e) of FFDCA authorizes EPA to establish, modify, or revoke tolerances, or exemptions from the requirement of a tolerance for residues of pesticide chemicals in or on raw agricultural commodities and processed foods.

III. Human Health Assessment

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 lignosulfonate chemicals are discussed in this unit.

A. Description of Lignosulfonate Materials

Lignin is an extremely complex naturally occurring phenolic polymer that is primarily made of three phenolic alcohols: Coniferyl, p-coumaryl, and synapyl alcohols. These alcohols are cross-linked to each other via a variety of different chemical bonds. The structure of lignin is somewhat undefined. However, it is lignin that

supplies the strength and rigidity to the cell wall of plants. Lignin is the glue-like substance that binds the cellulose fibers together. The lignin group of compounds makes up the second most abundant class of chemicals found in plants. Cellulose is the most abundant. According to information available on the internet (<http://www.chem.vt.edu/chem-dept/helm/3434WOOD/notes1/lignin.html>), the ratio of the alcohols determines the rigidity or flexibility of the plant's cell wall. "p-Coumaryl alcohol is a minor component of grass and forage type lignins. Coniferyl alcohol is the predominant lignin monomer found in softwoods.....Both coniferyl and sinapyl alcohols are the building blocks of hardwood lignin." The lignin content of softwoods are on

the order of 26–32% and of hardwoods 20–28%.

To make pulp and paper, various processes are used to release the cellulose, by removing the lignin from plant cells, by destroying the chemical bonds within the lignin. These processes produce by-products which are different in composition from the original lignin polymer. In one such process lignin reacts with sulfur dioxide to form lignosulfonic acid. Lignosulfonates can also be produced as the sodium, potassium, calcium, magnesium, zinc, or ammonium salts. Using other chemical processes lignosulfonate chemicals that have been oxidized or ethoxylated can be manufactured.

B. Previous Agency Action

On March 27, 1996, EPA's OPP published in the **Federal Register** (61 FR 13476) (FRL–5355–6) a proposed

rule to establish tolerance exemptions for oxidized pine lignin, sodium salt (CAS No. 68201–23–0). In that proposed rule the Agency described its review and evaluation of various toxicity data as follows: "The toxicological data show that pine lignin, sulfonated pine lignin as well as oxidized pine lignin or lignosulfonates are of very low acute toxicity ($LD_{50} > 2$ to > 5 g/kg in rats.....Pine lignin is classified as toxicity category IV in a skin irritation and eye irritation studies." The final rule establishing the tolerance exemption for oxidized pine lignin published in the **Federal Register** of June 19, 1996 (61 FR 31037) (FRL–3575–9).

C. Internet Search for Publicly Available Information

The Agency through its Interagency Agreement with the Department of

Energy's Oakridge National Laboratory conducted an extensive literature search. Over 20 publicly available websites, such as International Programme on Chemical Safety (IPCS), National Toxicological Program (NTP), National Library of Medicine's TOXNET, Agency for Toxic Substances and Disease Registry (ATSDR), and Organization for Economic Co-operation and Development (OECD), were searched using both names and CAS Nos. as search terms. It should be noted that these are reliable compilations of toxicity data. The search revealed little information for these compounds in the public literature. Table 2 of this unit summarizes the information that was retrieved. All of the following studies were conducted using lignosulfonic acid, sodium salt.

TABLE 2.—TOXICITY DATA FOR LIGNOSULFONIC ACID, SODIUM SALT (CAS No. 8061–51–6)

Species	Study type	Results
Rat/Wistar	16-Week oral toxicity	NOAEL = 2.83 male (M) 2.42 female (F) gram/kilogram/day (g/kg/day) LOAEL = 10.02 (M) 9.99 (F) g/kg/day based on statistically significant decreases in body weight, RBC (erythrocytes), Hb (hemoglobin), and hematocrit; significantly significant increases in total leucocyte count; absolute and relative liver, spleen, and kidney weights in males
Rat/Wistar	Acute oral toxicity in male and female rats	$LD_{50} > 40$ g/kg
Rabbit	21/28-Day dermal toxicity	non irritating to skin in rabbits
Guinea pig (albino)	Repeated dose toxicity (1–5 weeks)	NOAEL was not determined LOAEL = 1.740 g/kg/day based on ulceration of the colon in 50% of test animals
<i>Salmonella typhimurium</i> strains TA98, TA100, TA1535, TA1537	Gene mutation	Non-mutagenic—Ames with and without activation

D. Information from the Petitioner

The information submitted in the two petitions (6E4673 and 6E4674) by LignoTech consisted of the following:

TABLE 3.—TOXICITY INFORMATION

Chemical description	Study
Pine lignin, sodium salt	Acute oral rat; LD_{50} is greater than 2 g/kg
Sulfonated pine lignin, sodium salt	Acute oral rat; LD_{50} is greater than 2 g/kg
Oxidized pine lignin, sodium salt	Acute oral rat; LD_{50} is greater than 5 g/kg

TABLE 3.—TOXICITY INFORMATION—Continued

Chemical description	Study
Carboxylated lignosulfonate, calcium salt	Acute oral rat; LD_{50} is greater than 5 g/kg
Oxidized lignosulfonate, sodium salt	Acute oral rat; LD_{50} is greater than 5 g/kg
Oxidized lignosulfonate, sodium salt	Skin irritation; not irritating
Oxidized lignosulfonate, sodium salt	Eye irritation; not irritating

The petitioner supplied only the information in this unit, not the studies or source from which the information was extracted. Therefore, the Agency cannot review and evaluate any of this information. According to the petitioner, lignosulfonates are generally recognized as having low aquatic, avian, and mammalian toxicities. Sulfite liquors and cooking liquors are the raw materials obtained from the sulfite pulping of wood chips, with the main component of these liquors being sodium lignosulfonate, a derivative of the natural-occurring polymer, lignin.

E. Structure Activity Relationship (SAR) Assessment

The Agency traditionally begins its evaluation process for inert ingredients by searching publicly available

databases. However, the Agency believes that for certain chemicals it is possible to assess the chemical's toxicity with other evaluation tools which can include expert scientific judgement. Even if literature searches do not yield much toxicity data, given these other tools, the Agency believes that it is still possible to determine a "reasonable certainty of no harm."

SAR analysis is a useful tool for predicting toxicity and thus identifying chemicals which may present specific risk concerns and/or for which the value of generating additional data would be low. This analysis utilizes the chemical's structural similarity to other chemicals for which data are available. A discussion on the SAT process in the Office of Pollution Prevention and Toxics (OPPT) follows.

SAR assessments have been performed by OPPT for over 25 years. Under section 5 of the Toxic Substances Control Act (TSCA), the Agency must make a determination to restrict the manufacture or importation of the chemical within 90 days of the submission of a pre-manufacturing notice (PMN). The Agency must make either a "...may present an unreasonable risk to human health or the environment..." finding or show that the chemical "...is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the

substance...". However, section 5 of TSCA does not require any toxicity testing as a prerequisite for submission of PMNs. Thus, toxicological data are usually not available for review by the Agency. In response to the lack of toxicity data, and the mandated time frames, the Agency has relied on expert assessments to predict a chemical's toxicity.

For human health, the SAR process can be used to assess absorption and metabolism, mutagenicity, carcinogenicity, developmental and reproductive effects, neurotoxicity, system effects, immunotoxicity, sensitization, and irritation. This is a qualitative assessment using terms such as good, not likely, poor, moderate, or high. To judge the validity of these assessments, EPA examined the method in the Project on the Evaluation of (Quantitative) Structure Activity Relationships (EPA 743-R-94-001). Given only chemical structure information, the Structure Activity Team (SAT) in OPPT assessed 140 chemicals using their SAR assessment process. The results of their assessments were then compared to the "base set" data that the European Union (EU) had received on each chemical. The results indicated that the SAR assessments were "on target" 90% of the time for aquatic toxicity, and roughly 80% of the time for human health effects. For human health, the approximately 20% that were not "on target" were overestimates.

The SAT consists of expert scientists who evaluate the potential environmental fate, human health, and environmental hazards of these new chemicals. The scientific disciplines represented on the SAT are: Chemistry, environmental fate, ecotoxicity, absorption/metabolism, mutagenicity, carcinogenicity, developmental/reproductive toxicity, neurotoxicity, acute toxicity, and subchronic/chronic toxicity.

Thus, after an in-depth literature search revealed that there was not extensive information available on the lignosulfonates, OPP decided to utilize the SAT's expertise to evaluate/identify the potential risks to human health posed by the lignosulfonates, and the environmental fate, health, and environmental hazards of the lignosulfonates, while considering the information on lignosulfonic acid, sodium salt. The SAT process begins by verifying the chemical identity and structures of the requested chemicals and then estimating (modeling) the physical/chemical properties of the chemicals, if measured data are not available.

Table 4 of this unit contains an excerpt of the information on the physical/chemical properties which were used by the SAT to make the determination. (Information on all of the physical/chemical properties considered by the SAT is contained in paper format only in EDOCKET OPP-2004-0413).

TABLE 4.—COMPARISON OF CHEMICAL/PHYSICAL PROPERTIES FOR LIGNOSULFONIC ACID SODIUM SALT AND SODIUM SALT OXIDIZED (OBTAINED FROM THE SAT)

Chemical	Physical state	Boiling point	Water solubility (g/Liter (L))	Vapor pressure	Molecular weight
Lignosulfonic acid, sodium salt	Solid	>500	>500	<0.000001	10,000
Lignosulfonic acid, sodium salt, oxidized	Solid	>500	>500	<0.000001	10,000

The information used by the SAT indicate that these are high molecular weight, polymeric-type materials. After determining the physical/chemical properties, the SAT divided the 16 chemicals into 3 groups. Group 1 consisted of: Lignosulfonic acid, ammonium salt; lignosulfonic acid, calcium salt; lignosulfonic acid, magnesium salt; lignosulfonic acid, sodium salt; and lignosulfonic acid, potassium salt.

The SAR conclusions for Group 1 are as follows:

Absorption is nil for all routes based on the physical/chemical properties.

There is concern for irritation and possible corrosion to the GI (gastrointestinal) tract based on data provided for sodium lignosulfonate (guinea pig 14–28 day oral drinking water LOEL = 1.7 g/kg/day with colonic ulceration. No pH values were provided for the lignosulfonic acid or its salts; therefore, SAT members made the assumption that the free acid would have a very low pH value and that the salts could have high pH values depending on the amount of and the manner in which the counter-ion reacted or complexed with the acid. Based on this assumption there is a

concern for irritation to skin, eyes, and lungs. There is also concern for lung toxicity if inhaled based on potential lung overload for high molecular weight polymers. The SAT determined that Group 1 lignosulfonates are of low-moderate concern for human health effects.

Group 2 consisted of lignosulfonic acid, zinc salt. The SAT's human health assessment for lignosulfonic acid, zinc salt are identical to Group 1's with the following addition. The inclusion of zinc in the lignosulfonate polymer results in concerns for developmental toxicity and immunotoxicity at high

doses, as well as concerns for asthma and mutagenicity. However, the SAT determined that lignosulfonic acid, zinc salt is also of low-moderate concern for human health effects.

Group 3 consisted of: Lignin, alkali reaction products with disodium sulfite and formaldehyde; lignin, alkali reaction products with formaldehyde and sodium bisulfite; ethoxylated lignosulfonic acid, sodium salt; lignin, alkali oxidized, sodium salt; lignin, alkali; lignosulfonic acid, sodium salt, polymer with formaldehyde and phenol; sulfite liquors and cooking liquors, spent, oxidized; lignosulfonic acid, sodium salt, oxidized; and lignosulfonic acid. The SAT's human health assessment for this group of lignosulfonate chemicals was identical to the SAT determinations for Group 1.

F. Data obtained via the High Production Volume (HPV) Challenge Program

The test plan for spent pulping liquor (CAS No. 66071-92-9) was submitted to OPPT on January 29, 2001 by the American Forest & Paper Association (AF&PA). (See <http://www.epa.gov/chemrtk/afpa/c12936.pdf>) On February 21, 2003, the final data summary was submitted. (See <http://www.epa.gov/chemrtk/afpa/c12936fds.pdf>) While spent pulping liquor is not proposed for tolerance exemption in this document, it is noted that one of the chemicals proposed for tolerance exemption is spent liquors and cooking liquid, spent, oxidized. AF&PA noted in their data summary, that spent pulping liquor is very alkaline in nature, with a pH ranging from 11.5 to 13.5. The composition varies, but includes pulping chemicals, cellulose, hemicellulose, and lignin. Given the high pH, testing could be performed on only very dilute solutions, so the only toxicity testing described in the submission are two mutagenicity tests. The results of the bacterial reverse mutation test indicated that spent pulping liquor is non-mutagenic in that test. In a chromosomal aberration assay with Chinese hamster ovary cells (*in vitro*), spent pulping liquor was clastogenic with and without activation. Concentrations of 2,500 µg/mL with activation and 5,000 µg/mL without activation were judged overtly toxic to the cultures.

G. Conclusions

The toxicity data available to the Agency indicate that the lignosulfonates are of very low toxicity. The oral acute LD₅₀s supplied by the petitioner are all greater than 2 g/kg. The toxicological data located in the public literature is

for sodium lignosulfonate. Repeated dose studies retrieved from open literature indicate NOAELs and LOAELs expressed as g/kg/day instead of the usual unit in most toxicity studies reviewed by the Agency of milligram (mg)/kg/day. There is some very unsubstantiated information that lignosulfonate materials given to rats before, during, and after mating at doses as high as 1,500 mg/kg/day did not cause adverse effects on reproduction or offspring. But at a dose level of 500 mg/kg/day there were histopathological changes in the lymph nodes of the mothers. Given the quality and quantity of information available, OPP needed additional information to complete its assessment of the lignosulfonate chemicals.

As a group, the SAR assessments did not identify any concerns for mutagenicity or carcinogenicity for the lignosulfonate chemicals. Based on the physical/chemical properties, and particularly on the large molecular weights of the lignosulfonate chemicals, the SAT believes that when considered as a group, the lignosulfonates are not absorbed via any route. This is due to the fact, that generally, polymer-type materials such as lignosulfonates of these higher molecular weights would be poorly absorbed through the intact gastrointestinal tract or through intact human skin.

As a group, one of the health concerns for lignosulfonate chemicals is for inhalation to the deep lung (a lung overload effect), which could occur if lignosulfonate chemicals were to be used either as a powder or as an aerosol. Other concerns identified by the SAT are for irritation to skin, eyes, and lungs, which was based on the assumption that some of these chemicals could have a low pH and therefore display effects consistent with those of an acid. The lung and irritation effects are adequately handled through acute end-product testing to determine any needed personal protective equipment.

The lignosulfonic acid, zinc salt was judged to be of more concern than any of the other lignosulfonate salts. According to the SAT, the inclusion of zinc can result in concerns for developmental toxicity and immunotoxicity at high doses, as well as concerns for asthma and mutagenicity. However, zinc is also a needed nutrient.

Counter-ions such as calcium, potassium, sodium, magnesium, and zinc are required for proper functioning of human biological systems. Thus, the human body does have an effective means of processing them. Zinc is an essential element in the nutrition of man. It functions as an integral part of

numerous enzymes. The daily intake for an adult ranges from 14 to 20 mg/day. The recommended dietary allowance (RDA) for adult men and women is 15 mg/day; however, the amount of zinc needed by the body changes throughout life. The Food and Nutrition Board of the United States evaluated zinc dietary allowances and recommended zinc as follows: 2 mg for infants 0.5 years, 5 mg for 0.5–1.0 years, 10 mg for children 1–10 years, 15 mg for men and women 11–51+ years, 20 mg for pregnant women, and 25 mg for lactating women. Deficiencies of zinc can cause illness. Given the incorporation of zinc into a polymeric-type high molecular weight chemical, which is then not well-absorbed by the human body, it is unlikely that the high doses of zinc at which adverse effects are possible would be reached. Without the concerns for the zinc counter-ion, as a group the SAT judged that there were no structural similarities of lignosulfonate chemicals to any known developmental toxicants.

IV. 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).

A. Dietary Exposure

Several of the lignosulfonates have applications in food and animal feed products. Monographs describing purity requirements and analytical procedures for both lignosulfonic acid, calcium salt and lignosulfonic acid, sodium salt are published in the *Fourth Edition of the Food Chemicals Codex*. Various salts of lignosulfonic acid have been approved by FDA as secondary direct food additives, components of adhesives, components of paper and paperboard, and adjuvants for glue. Lignosulfonate chemicals can also be used as a pelletizing agent or binder in processed animal feed items. Therefore, animals can consume lignosulfonates as part of their feed mix, and then these animals are consumed by humans. Thus, there is on-going human dietary exposure.

B. Drinking Water

To assess the presence of the lignosulfonate chemicals in drinking water, two reviews are available. A review performed by OPP determined that the various salts of lignosulfonic

acid are soluble to very highly water soluble depending on the cation. Once in water dissociation of the cation is expected depending on pH. These lignosulfonates are not expected to be mobile in terrestrial environments, moving equally with the water and sediment phase to surface water. Ground water migration is not likely. Once in water, the dissociated cation and anion are likely to remain in dissolution. The available information suggest that lignosulfonates may be persistent in aquatic environment of low microbial activity and much less persistent in environments with ample microbial activity.

The SAR assessment performed by OPPT determined that as a group the lignosulfonates were of low concern for exposure via drinking water. Though the time for complete aerobic degradation is predicted to be months, the lignosulfonates are strongly adsorbed to soils and sediments due to their high-molecular weights. This strong binding minimizes the availability of these chemicals for migration to ground water supplies and thus reduces the potential for residues of lignosulfonates to be present in drinking water.

C. Other Non-Occupational

Lignosulfonates have many uses in industrial applications. According to the Lignin Institute website, lignosulfonates can be used as an adhesive (a binder), a dispersant to prevent the clumping and settling of undissolved particles in suspensions, an emulsion stabilizer, and as a sequestrant for water treatments for boilers and cooling systems. Lignosulfonates are used for dust control and surface stabilization on roads.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCFA 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 for any of the lignosulfonate chemicals. As a group, the lignosulfonates do not appear to produce any toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that any of the lignosulfonate 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 OPP 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/>.

VI. Determination of Safety

The available data from the open literature describes chemicals which exhibit effects at doses that are in the grams per kilogram per day. Additionally, the Agency's understanding of the polymeric nature of these chemicals indicates nil absorption, and there is a finding of low-moderate concern for human health from the SAR assessments. Based on all of the available information, EPA concludes that these lignosulfonate chemicals do not pose an appreciable risk under reasonably foreseeable circumstances. Accordingly, EPA finds that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to these lignosulfonate chemicals.

Section 408 of FFDCFA 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 unless EPA concluded that a different margin of safety will be safe for infants and children. The SAR assessments did not indicate any concerns for developmental toxicity for the lignosulfonate chemicals, other than for the zinc counter-ion. Given the incorporation of zinc into a polymeric-type high molecular weight chemical, which is then not well-absorbed by the human body, it is unlikely that the high doses of zinc at which adverse effects can occur would be reached. Due to the expected low oral toxicity due to the nil absorption of the lignosulfonates, a safety factor analysis has not been used to assess the risk. For the same reasons, the additional tenfold safety factor for the protection of infants and children is unnecessary.

VII. 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 lignosulfonate chemicals for endocrine effects may be required.

B. Analytical Method

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

C. Existing Tolerances

Currently, there are seven tolerance exemptions for lignosulfonate chemicals. In 40 CFR 180.910: Ethoxylated lignosulfonic acid, sodium salt; lignosulfonate, ammonium, calcium, magnesium, potassium, sodium, and zinc salts; oxidized pine lignin, sodium salt; pine lignin. There are also in 40 CFR 180.930: Lignosulfonate, ammonium, calcium, magnesium, potassium, sodium, and zinc salts; oxidized pine lignin, sodium salt; and pine lignin. The Agency is proposing to revise these tolerances.

D. International Tolerances

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

VIII. Conclusions

Based on the Agency's review and evaluation of the available information on the toxicity of lignosulfonate chemicals and considering the SAR assessments, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of these 22 lignosulfonate chemicals. The Agency finds that exempting these 22 lignosulfonate chemicals from the requirement of a tolerance will be safe.

IX. Statutory and Executive Order Reviews

This proposed rule establishes 32 exemptions from the requirement for a tolerance under section 408(d) of FFDCFA. 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 proposed

rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed 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). This proposed 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). The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental organizations. After considering the economic impacts of this proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. Establishing an exemption from the requirement of a pesticide tolerance (or, expanding and

consolidating a tolerance exemption, as is proposed), is in effect, the removal of a regulatory restriction on pesticide residues in food and thus such an action will not have any negative economic impact on any entities, including small entities. 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 proposed 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 FFDCFA. For these same reasons, the Agency has determined that this proposed 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 proposed 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 proposed rule.

List of Subjects in 40 CFR Part 180

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

Dated: February 5, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 would continue to read as follows:

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

§ 180.910 [Amended]

2. Section 180.910 is proposed to be amended by removing the following entries from the table: Ethoxylated lignosulfonic acid, sodium salt; lignosulfonate, ammonium, calcium, magnesium, potassium, sodium, and zinc salts; oxidized pine lignin, sodium salt; and pine lignin.

3. Section 180.910 is proposed to be amended by adding alphabetically the following entries to the table to read as follows:

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

* * * * *

Inert ingredients	Limits	Uses
Lignin (CAS No.9005-53-2)	surfactant, related adjuvants of surfactants
Lignin, alkali (CAS No. 8068-05-1)	Surfactant, related adjuvants of surfactants
Lignin, alkali, oxidized, sodium salt (CAS No. 68201-23-0)	Surfactant, related adjuvants of surfactants
Lignin alkali, reaction products with disodium sulfite and formaldehyde (CAS No. 105859-97-0).	Surfactant, related adjuvants of surfactants
Lignin alkali, reaction products with formaldehyde and sodium bisulfite (CAS No. 68512-35-6).	Surfactant, related adjuvants of surfactants
Lignosulfonic acid (CAS . No. 8062-15-5)	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, ammonium calcium salt (CAS No. 12710-04-2).	Surfactant, related adjuvants of surfactants

Inert ingredients	Limits	Uses
Lignosulfonic acid, ammonium magnesium salt (CAS No. 123175-37-1).	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, ammonium salt (CAS No. 8061-53-8)	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, ammonium sodium salt (CAS No. 166798-73-8).	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, calcium magnesium salt (CAS No. 55598-86-2).	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, calcium salt (CAS No. 8061-52-7)	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, calcium sodium salt (CAS No. 37325-33-0).	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, ethoxylated, sodium salt (CAS No. 68611-14-3).	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, magnesium salt (CAS No. 8061-54-9)	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, potassium salt (CAS No. 37314-65-1)	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, sodium salt (CAS No. 8061-51-6)	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, sodium salt, oxidized (CAS No. 68855-41-4).	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, sodium salt, polymer with HCHO and phenol (CAS No. 37207-89-9).	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, sodium salt, sulfomethylated (CAS No. 68512-34-5).	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, zinc salt (CAS No. 57866-49-6)	Surfactant, related adjuvants of surfactants
Sulfite liquors and cooking liquid, spent, oxidized (CAS No. 68514-09-0).	Surfactant, related adjuvants of surfactants

* * * * *

§ 180.930 [Amended]

4. Section 180.930 is proposed to be amended by removing the following entries from the table: Lignosulfonate, ammonium, calcium, magnesium,

potassium, sodium, and zinc salts; oxidized pine lignin, sodium salt; and pine lignin.

5. Section 180.930 is proposed to be amended by adding alphabetically the

following entries to the table to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
Lignin (CAS No. 9005-53-2)	Surfactant, related adjuvants of surfactants
Lignin, alkali (CAS No. 8068-05-1)	Surfactant, related adjuvants of surfactants
Lignin, alkali, oxidized, sodium salt (CAS No. 68201-23-0)	Surfactant, related adjuvants of surfactants
Lignin alkali, reaction products with disodium sulfite and formaldehyde (CAS No. 105859-97-0).	Surfactant, related adjuvants of surfactants
Lignin alkali, reaction products with formaldehyde and sodium bisulfite (CAS No. 68512-35-6).	Surfactant, related adjuvants of surfactants
Lignosulfonic acid (CAS No. 8062-15-5)	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, ammonium calcium salt (CAS No. 12710-04-2).	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, ammonium magnesium salt (CAS No. 123175-37-1).	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, ammonium salt (CAS No. 8061-53-8)	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, ammonium sodium salt (CAS No. 166798-73-8).	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, calcium magnesium salt (CAS No. 55598-86-2).	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, calcium salt (CAS No. 8061-52-7)	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, calcium sodium salt (CAS No. 37325-33-0).	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, ethoxylated, sodium salt (CAS No. 68611-14-3).	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, magnesium salt (CAS No. 8061-54-9)	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, potassium salt (CAS No. 37314-65-1)	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, sodium salt (CAS No. 8061-51-6)	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, sodium salt, oxidized (CAS No. 68855-41-4).	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, sodium salt, polymer with HCHO and phenol (CAS No. 37207-89-9).	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, sodium salt, sulfomethylated (CAS No. 68512-34-5).	Surfactant, related adjuvants of surfactants
Lignosulfonic acid, zinc salt (CAS No. 57866-49-6)	Surfactant, related adjuvants of surfactants

Inert ingredients	Limits	Uses
* * * Sulfite liquors and cooking liquid, spent, oxidized (CAS No. 68514-09-0). * * *	* * * *	* * Surfactant, related adjuvants of surfactants * *

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