Review Under Executive Order 13132, Federalism, 64 FR 43255 (August 4, 1999)

Review under Executive Order 13132 requires that agencies review regulations for federalism effects on the institutional interest of states and local governments, and, if the effects are sufficiently substantial, prepare a Federal assessment to assist senior policy makers. This proposed rule will not have any direct effects on State and local governments within the meaning of the Executive Order. Therefore, the regulation requires no federalism assessment.

List of Subjects in 36 CFR Part 1258

Archives and records.

For the reasons stated in the preamble, NARA amends 36 CFR part 1258 as follows:

PART 1258—FEES

1. The authority citation for part 1258 remains as follows:

Authority: 44 U.S.C. 2116(c) and 2307.

2. Revise § 1258.16 to read as follows:

§ 1258.16 What is NARA’s refund policy?

Due to various factors, it is occasionally difficult for NARA to make a legible reproduction. NARA will notify customers and ask for approval to proceed if we anticipate a reproduction of questionable legibility. As a result, NARA does not provide refunds except in special cases. If a customer requests a refund, we review the order to determine if we properly notified the customer of the questionable nature of the original and if the product is a true representation of the original. If the product is a true representation of the original, we will not issue a refund. If you feel we processed your order incorrectly or it contains errors, please contact us within 120 days of your order date to have your issue verified. Once we verify the issue, we will correct the error and resend the documents. If we cannot correct the error, you will receive a refund.

Dated: March 20, 2016.

David S. Ferriero,
Archivist of the United States.

[FR Doc. 2016–07149 Filed 3–29–16; 8:45 am]

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180


Salicylaldehyde; 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 salicylaldehyde (2-hydroxybenzaldehyde, CAS Reg. No. 90–02–8) when used as an inert ingredient (penetration aid) in pesticide formulations applied to growing crops and raw agricultural commodities under 40 CFR 180.910 at a concentration not to exceed 14% by weight of the pesticide formulation. Ag-Chem Consulting LLC, on behalf of Omex Agrifluids 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 permissable level for residues of salicylaldehyde.

DATES: This regulation is effective March 30, 2016. Objections and requests for hearings must be received on or before May 31, 2016, 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 (EPA–HQ–OPP–2015–0019) 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), West William Jefferson Clinton 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) 305–8605. Please review the visitor instructions and additional information about the docket available at http://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7000; email address: REDRNotice@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?


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–2015–0019 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 May 31, 2016. 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 (excluding any Confidential Business Information (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 the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–
methods:

17612 Federal Register

other information whose disclosure is

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instructions for submitting comments.

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agencies; propellants in aerosol

wetting, spreading, and dispersing

Carrageenan and modified cellulose;

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 cellulose; wetting,

spreading, and dispersing agents;

propellants in aerosol

I. Determination of Safety

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 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 exemption is “safe.”

Section 408(c)(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 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 (Nexus) (structural activity

relationship) report, there are no

structural alerts for carcinogenicity.

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 salicylaldehyde 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.

The acute oral toxicity of

salicylaldehyde was examined in male

rats and mice. The general oral lethal

amount of salicylaldehyde is estimated
to be 500 mg/kg in mice. The dermal

LD50 for salicylaldehyde was
determined to be greater than 23,000

mg/kg. Dermal irritation studies found

salicylaldehyde to be irritating, with

eschar formation and scarring 14 days

after administration.

No adverse effects attributable to a

single exposure to salicylaldehyde were

seen in the toxicity databases. In a

combined repeated dose toxicity study

with the reproduction/developmental
toxicity screening test, toxicity was not

observed in parental animals nor in

reproductive parameters at doses up to

160 mg/kg/day, the highest dose tested.

Fetal susceptibility was observed.

Reduced body weight and offspring

mortality after 4 days of nursing were

observed at 160 mg/kg/day. The NOAEL

was 40 mg/kg/day. There was no

evidence of neurotoxicity or

immunotoxicity in the combined

repeated dose toxicity with the

reproduction/developmental toxicity

screening test.

Salicylaldehyde was negative for

mutagenicity in the Ames test and gave

a positive response in the chromosome

aberrations test using Chinese hamster

cells (in vitro). An in vivo micronucleus

assay was negative. Since the in vivo

study is more reliable than the in vitro

assays, the weight of evidence suggests

that salicylaldehyde is unlikely to be

mutagenic.

There are no cancer studies available for

salicylaldehyde. According to a

DEREK (Nexus) (structural activity

relationship) report, there are no
Based on predicted rapid metabolism and excretion, lack of specific target organ toxicity in the repeat dose toxicity study, lack of mutagenicity concerns, and lack of any structural alerts for carcinogenicity, salicylaldehyde is not expected to be carcinogenic to humans at anticipated dietary concentrations. The metabolism of salicylaldehyde in rabbits demonstrated that 75% of single dose of salicylaldehyde was excreted in the urine as glucuronic acid and sulfate conjugates of vanillic acid.

**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 acute toxicological endpoint of concern has been identified for salicylaldehyde. On the basis of the repeated dose and reproductive/developmental toxicity screening study, a no observed adverse effect level (NOAEL) for offspring toxicity for salicylaldehyde was 40 mg/kg bw/day based on reduced body weight and increased mortality in pups at 160 mg/kg/day. The standard 10X factors for intra- and inter-species were applied in establishing the chronic reference dose (cRfD) of 0.4 mg/kg/day (40 mg/kg/day/100). Based on the reduced FQPA Safety Factor for salicylaldehyde of 1X, the chronic population adjusted dose (cPAD) is equivalent to the chronic reference dose (cRfD) at 0.4 mg/kg/day.

The chronic oral NOAEL is also applicable to the short- and intermediate-term dermal and inhalation exposure routes.

**C. Exposure Assessment**

1. Dietary exposure from food and feed uses. In evaluating dietary exposure to salicylaldehyde, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from salicylaldehyde in food as follows:

   Acute dietary assessments take into account exposure estimates from dietary consumption of food and drinking water. Chronic dietary assessments take into account dietary food and drinking water. The Agency assessed the dietary exposures to salicylaldehyde as an inert ingredient used in pesticide formulations applied to growing crops and livestock. No adverse effects attributable to a single exposure to salicylaldehyde were seen in the toxicity databases; therefore, an acute dietary risk assessment is not appropriate.

   In conducting the chronic dietary exposure assessment to salicylaldehyde an inert ingredient used in pesticide formulations applied to growing crops, raw agricultural commodities, and livestock, the Dietary Exposure Evaluation Model/food commodity intake database (DEEM–FCID) TM, Version 3.16 was used. EPA used food consumption information from the U.S. Department of Agriculture’s National Health and Nutrition Examination Survey, What We Eat in America, (USDA/NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. As to residue levels in food, no residue data were submitted for salicylaldehyde. In the absence of specific residue data, EPA has developed an approach that uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest 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 Polyoxyxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts.” [D361707, S. Piper, 2/25/08] and can be found at http://www.regulations.gov in docket ID number EPA–HQ–OPP–2008–0738.

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 salicylaldehyde, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. 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).

There are no current or proposed residential uses for salicylaldehyde; however, it is possible that salicylaldehyde may be used as an inert ingredient in pesticide products. A highly conservative residential exposure assessment was performed in which it was assumed that all residential use pesticide products would contain salicylaldehyde as an inert ingredient. A complete description of the approach used to assess possible residential exposures from salicylaldehyde can be found in http://www.regulations.gov in document “Salicylaldehyde; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations,” pp. 15 in docket ID number EPA–HQ–OPP–2015–0019.

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 or exemption from 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 salicylaldehyde to share a common mechanism of toxicity with any other substances, and salicylaldehyde does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that salicylaldehyde 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, see EPA’s Web site at http://www.epa.gov. To evaluate the cumulative effects of such chemicals, see EPA’s Web site at http://www.epa.gov.
This study is being used to establish the defined offspring toxicity NOAEL and susceptibility since there is a clear, well-defined offspring toxicity screening test, offspring toxicity with the reproduction/developmental toxicity screening test, and increased mortality in the case of threshold effects to account for cumulative.

There is evidence of increased neurotoxicity in the available studies, including the battery of acute studies, mutagenicity studies and water with short-term residential exposures to salicylaldehyde. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to salicylaldehyde from food and water will utilize 13% of the cPAD for the U.S. population and 49% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure.

3. Short- and intermediate-term risk. Short- and intermediate-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Salicylaldehyde may be used as inert ingredients in pesticide products that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to salicylaldehyde. Using the exposure assumptions described in this unit, EPA has concluded the combined short- and intermediate-term food, water, and residential exposures result in short- and intermediate-term aggregate MOEs of 430 for adults and 170 for children (1–2 years old). Because EPA’s level of concern for salicylaldehyde is a MOE of 100 or below, these MOEs are not of concern.

4. Aggregate cancer risk for U.S. population. Based on a DEREK structural alert analysis and the lack of mutagenicity, salicylaldehyde not expected to pose a cancer risk to humans.

5. Determination of safety section. Based on these risk assessments, EPA concludes that there is reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to salicylaldehyde residues.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for residues salicylaldehyde (CAS Reg. No. 90–02–8) when used as an inert ingredient (penetration aid) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest at a concentration not to exceed 14% by weight of the pesticide formulation.

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of 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 action has been exempted from review under Executive Order 12866, this action 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 action 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 exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), do not apply.

This action 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 62249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 et seq.).

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 (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.), 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 the rule in the Federal Register. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

<table>
<thead>
<tr>
<th>Inert ingredients</th>
<th>Limits</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salicylaldehyde (CAS Reg. No. 90–02–8).</td>
<td>Not to exceed 14% by weight of pesticide formulation</td>
<td>Penetration aid.</td>
</tr>
</tbody>
</table>

List of Subjects in 40 CFR Part 180

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

Dated: March 22, 2016.

Susan Lewis,
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:


2. In § 180.910, add alphabetically the inert ingredient “Salicylaldehyde”, to the table to read as follows:

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

* * * * *

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain...