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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0019; FRL-9944-12]

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 permissible level for residues of salicylaldehyde.

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], 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-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) 305-5805. 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.,

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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://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCFA 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 *[insert date 60 days after date of publication in the **Federal Register**]*. 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-2015-0019, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *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.html>. 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 April 6, 2015 (80 FR 18327) (FRL-9924-00), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10777) by Ag-Chem Consulting LLC, 12208 Quinque Lane, Clifton, VA 20124 on behalf of Omex Agrifluids, 24730 Avenue 13, Madera, CA 93637. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of salicylaldehyde (CAS Reg. No. 90-02-8) when used as an inert ingredient (penetration aid) in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest at a concentration not to exceed 14% by weight of the pesticide formulation. That document referenced a summary of the petition prepared by Ag-Chem Consulting LLC, on behalf of Omex Agrifluids., the petitioner, which is available in the docket, <http://www.regulations.gov>. 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 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 of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for salicylaldehyde including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with salicylaldehyde 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 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 bodyweight 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 structural alerts for carcinogenicity. 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 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.

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. *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).

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 and to evaluate the cumulative effects of such chemicals, see EPA's website 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 is evidence of increased susceptibility of infants and children due to exposure to salicylaldehyde. In a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test, offspring toxicity was manifested as decreased body weights and increased mortality in the absence of maternal toxicity at doses up to 160 mg/kg/day. The offspring toxicity NOAEL was 40 mg/kg/day. However, there are no to low concerns for this susceptibility since there is a clear, well defined offspring toxicity NOAEL and this study is being used to establish the cRfD.

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. The toxicity database for salicylaldehyde includes the battery of acute studies, mutagenicity studies and a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test.

ii. There is no evidence of neurotoxicity in the available studies, therefore there is no need for a developmental neurotoxicity study.

iii. There is no evidence of immunotoxicity in the available database, therefore there is no need for an immunotoxicity study

iv. There are low to no concerns for the increased susceptibility seen in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test.

v. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 14% by weight in the formulation (the maximum allowable use rate) and tolerance-level residues.

EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to salicylaldehyde 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 salicylaldehyde.

E. Aggregate Risks and Determination of Safety

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, salicylaldehyde 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 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.

V. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation. EPA is establishing a limitation on the amount of salicylaldehyde that may be used in pesticide formulations applied to growing crops. 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 formulation for use on growing crops for sale or distribution that exceed 14 % of salicylaldehyde.

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 crops at no more than 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 FFDC 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 FFDC 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 67249, 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).

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:

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

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.

* * * * *

Inert ingredients	Limits	Uses
* *	* *	* * *
Salicylaldehyde (CAS Reg. No. 90-02-8)	Not to exceed 14% by weight of pesticide formulation.	Penetration aid
* *	* *	* * *

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