

July 1995 RED	Syngenta Request	Amendments to 1995 RED
All workers required to wear a double layer of clothing (coveralls over long sleeved shirt, long pants), chemical resistant gloves, chemical resistant footwear plus socks, chemical resistant headgear for overhead exposure, and a chemical resistant apron when cleaning equipment, mixing or loading)	Reduced PPE requirements due potential for heat stress to field workers and applicators	All workers must continue to wear protective footwear and coveralls over a single layer of clothes (products with a dermal toxicity of III or IV may reduce PPE to protective footwear and coveralls over short pants and short sleeve shirts). Mixers, loaders and hand applicators must wear chemical resistant gloves, while applicators who are operating closed cab equipment are not required to wear chemical resistant gloves due to MOEs over 1,000.
Respirators for mixing and loading	No respirator requirements for mixing and loading due to potential for heat stress	Respirator requirement for mixer/loaders reduced to a face shield to prevent droplets from entering the eyes, mouth or nose areas
Closed mixing system for aerial applications.	Open mixing system for aerial applications.	Closed mixing/loading requirements remain for aerial applications.
7-Day restricted entry interval (REI) for products used under the Worker Protection Standard (WPS) unless there is no contact with treated surfaces (such as mechanical harvesting)	4-Hour REI for potato desiccation and seed crops	REI reduced to 24 hours for all WPS uses, based on default reentry analysis findings of MOEs between 150 and 1,500 and a toxicity category II for eye irritation
4-Day REI for non-WPS uses other than aquatic and spot treatment at residential sites	REI when spray is dry for non-WPS uses	REI reduced to "when sprays are dry" for non-WPS uses, also based on default reentry analysis
Prohibition of broadcast spray applications for homeowner and residential uses	Broadcast spray applications for homeowner and residential uses	Generic data requirements have been fulfilled for residential broadcast spray uses. Broadcast spray applications for homeowner and residential uses for end-use products will be decided on a case-by-case basis upon review of end-use product toxicity, based on short-term exposure and individual risk assessments.

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

The legal authority for this decision falls under FIFRA, as amended in 1988 and 1996. Section 4(g)(2)(A) of FIFRA directs that, after submission of all data concerning a pesticide active ingredient, "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration," and either reregister products or take other "appropriate regulatory action."

#### List of Subjects

Environmental protection, Chemicals, Aquatic herbicides.

Dated: September 5, 2002.

**Lois Rossi,**

*Director, Special Review and Reregistration Division, Office of Pesticide Programs.*

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**BILLING CODE 6560-50-S**

### ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0201; FRL-7194-5]

#### Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

**DATES:** Comments, identified by docket ID number OPP-2002-0201, must be received on or before October 18, 2002.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the

**SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-0201 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Bipin Gandhi, Registration Division (7505C), Office of Pesticide

Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-8380; e-mail address: gandhi.bipin@epa.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

##### A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS Codes	Examples of potentially affected entities
Industry	111 112 311  32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to

assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?*

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP-2002-0201. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

*C. How and To Whom Do I Submit Comments?*

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP-2002-0201 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs

(OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: [opp-docket@epa.gov](mailto:opp-docket@epa.gov), or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket ID number OPP-2002-0201. Electronic comments may also be filed online at many Federal Depository Libraries.

*D. How Should I Handle CBI That I Want to Submit to the Agency?*

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

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

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

**II. What Action is the Agency Taking?**

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

**List of Subjects**

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 11, 2002.

**Peter Caulkins,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

**Summary of Petition**

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary intentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

**Hampshire Chemical Corporation**

2E6491

EPA has received a pesticide petition (2E6491) from Hampshire Chemical Corporation, 2 East Spit Brook Road, Nashua, NH 03060 proposing, pursuant to section 408(d) of the FFDCFA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to amend an existing exemption from the requirement of a tolerance for *N*-acyl sarcosines and sodium *N*-acyl sarcosinates when used at levels not to exceed 10% as inert ingredients (surfactants) in pesticide formulations. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCFA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

**A. Residue Chemistry**

1. *Analytical method.* Hampshire Chemical Corporation is requesting an exemption from the requirement of a tolerance without any numerical limitation; therefore, an analytical method is not required for enforcement purposes for *N*-acyl sarcosines and sodium *N*-acyl sarcosinates.

2. *Magnitude of residues.* Based upon the proposed use as an inert ingredient in glyphosate formulations, dietary (food) exposure to *N*-acyl sarcosines and/or sodium *N*-acyl sarcosinates would not be expected to exceed the theoretical maximum residue concentration (TMRC) of glyphosate to the U.S. population of 0.03 milligrams/kilogram/day (mg/kg/day). Dietary exposure to *N*-acyl sarcosines and/or sodium *N*-acyl sarcosinates at or below these levels would not result in any increases in the normal sarcosine blood serum concentrations found in humans.

**B. Toxicological Profile**

1. *Acute toxicity.* Acute oral toxicity of sodium *N*-lauroyl sarcosinate was evaluated in male rats. Ten groups of 10 rats per dose received a bolus dose of between 250 mg/kg and 2,500 mg/kg *N*-lauroyl sarcosinate in an aqueous solution. The lethal dose (LD<sub>50</sub>) was approximately 2,175 mg/kg.

2. *Genotoxicity.* An original study examining the mutagenicity of various cosmetic ingredients reported that *N*-lauroyl sarcosine is not mutagenic in the Ames assay.

3. *Reproductive and developmental toxicity.* Reproductive and developmental effects are not expected to occur through the use of *N*-acyl sarcosines as inert ingredients in

pesticide formulations. These substances have a long history of human exposure, they have been used extensively in a variety of consumer products, and no such adverse effects have been reported. Potential reproductive toxicity was evaluated in the chronic oral exposure study, and the authors report no effects on fertility between treated and control rat groups.

4. *Subchronic toxicity.* A 2-year study of the oral toxicity of sodium *N*-lauroyl sarcosinate was conducted on rats. An interim sacrifice 3 months into the study provides toxicity data to support characterization of subchronic toxicity. At the 3-month interval, there were no significant differences in pathology, fertility, mortality, hematology, or weights between experimental animals in any group and control animals. The absence of adverse effects at any dose level up to 90 days supports a no observed adverse effect level (NOAEL) of 1,000 mg/kg day. Subchronic dermal toxicity studies have not been performed on *N*-acyl sarcosinates, though three studies were conducted to evaluate *N*-acyl sarcosinates for potential skin irritation and sensitization. *N*-lauroyl sarcosinate was tested for irritation on rabbits and sensitization on guinea pigs, and *N*-myristoyl sarcosinate was evaluated for potential irritation on rabbits. Rabbits were treated daily over a 14-day period with sodium *N*-lauroyl sarcosinate powder or a 20% w/v solution of sodium *N*-lauroyl sarcosinate. No evidence of dermal toxicity was observed. Guinea pigs were treated by intradermal injection of 0.01% aqueous solution of sodium *N*-lauroyl sarcosinate every other day for a total of 10 injections, followed by 3 weeks of no treatment before receiving a challenge injection. No reactions were observed at any time in these animals and no evidence of toxicity was observed from the injection. A formulation containing 30% sodium *N*-myristoyl sarcosinate in aqueous solution was applied topically to abraded skin of rabbits. Very slight to well-defined erythema and slight to very slight edema were observed, resulting in a mean dermal irritation score of 1.7. The minimal mean score required for classification of material as a skin irritant is 5.0; therefore, sodium *N*-myristoyl sarcosinate is not a primary skin irritant. Overt dermal toxicity was not observed in any of these studies.

5. *Chronic toxicity.* A 2-year study of the oral toxicity of sodium *N*-lauroyl sarcosinate was conducted on rats. The dose levels were: 100 mg/kg for 6 months, followed by 4,000 mg/kg for the remaining 18 months, and other dose levels throughout the study were: 400 or

1,000 mg/kg/day. After 2 years, a slight but significant pathology was observed in animals that received 1,000 mg/kg throughout the study and 4,000 for the last 18 months of the study. The pathology observed was hyperplasia of the stratified epithelium with excess keratin formation of the cardiac mucosa of the stomach.

6. *Animal metabolism.* *N*-acyl sarcosines and sodium *N*-acyl sarcosinates form a large class of chemical compounds where the acyl group is derived from fatty acids such as lauric, oleic and stearic acid and/or derived from the combined fatty acids of coconut oil. *N*-acyl sarcosine and sodium *N*-acyl sarcosinates are metabolized by humans to sarcosine and the corresponding fatty acids. Sarcosine is ubiquitous in biological materials and is present in such foods as egg yolks, turkey, ham, vegetables, legumes, etc. Sarcosine is reported to be formed from dietary intake of choline and from the metabolism of methionine and is rapidly degraded to glycine, which, in addition to its importance as a constituent of protein, plays a significant role in various physiological processes as a prime metabolic source of components of living cells such as glutathione, creatine, purines and serine. The concentration of sarcosine in blood serum of normal human subjects is reported to be 1.59 + 1.08 micromoles per liter.

7. *Endocrine disruption.* There are no reports of any estrogenic or other adverse effects on the endocrine system in humans as a result of the use of *N*-acyl sarcosines and/or sodium *N*-acyl sarcosinates.

**C. Aggregate Exposure**

1. *Dietary exposure—food.* Based upon the ubiquitous presence of sarcosine in human tissue and the fact that *N*-acyl sarcosines are readily metabolized to the *N*-acyl sarcosines and their salts, Hampshire Chemical Corporation believes that exposure to this chemical will not pose a dietary risk under any foreseeable circumstances to the U.S. population, including infants and children. This conclusion is based on the inconsequential increases in dietary exposure resulting from its use as an inert ingredient in glufosinate ammonium, 2,4-D, atrazine and dicamba.

2. *Dietary exposure—drinking water.* Taking into account the proposed use in glufosinate ammonium, 2,4-D, atrazine, and dicamba formulations, Hampshire Chemical Corporation has concluded with reasonable certainty that residues of *N*-acyl sarcosines and/or the sodium *N*-acyl sarcosinates in drinking water

would be negligible, and that no harm will result from aggregate exposure to *N*-acyl sarcosines and/or the sodium *N*-acyl sarcosinates.

#### D. Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." EPA does not have, at this time, available data to determine whether *N*-acyl sarcosines and sodium *N*-acyl sarcosinates have a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, *N*-acyl sarcosines and sodium *N*-acyl sarcosinates do not share common toxic metabolites with other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that *N*-acyl sarcosines and sodium *N*-acyl sarcosinates have a common mechanism of toxicity with other substances.

#### E. Safety Determination

1. *U.S. population.* Based on the worst case assumption regarding the dietary risks resulting from exposure to *N*-acyl sarcosines and its salts when used at levels not to exceed 10% of pesticide formulations, residues of *N*-acyl sarcosines and their sodium salts would not be considered to be toxicologically significant. Based on the extensive use of *N*-acyl sarcosines and their sodium salts in various consumer products such as toothpastes, soaps, medicated skin cleaners and medicated shampoos; its physico-chemical properties; the fact that some of these chemicals have been approved for food use applications, and the review of its use, Hampshire Chemical Corporation does not believe that a potential for hazard exists when *N*-acyl sarcosines and their sodium salts are used in accordance with good agricultural practice.

2. *Infants and children.* FDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects in calculating a dose level that accounts for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through the use of margin of exposure analysis or

through using uncertainty factors (safety) in calculating a dose level that poses no appreciable risk to humans. Due to the ubiquitous nature of sarcosine in human tissue and food, a safety factor analysis in assessing the risk of *N*-acyl sarcosines and sodium *N*-acyl sarcosinates was not used. For the same reason, application of the additional safety factor for infants and children would not be appropriate.

#### F. International Tolerances

No Codex maximum residue levels have been established for *N*-acyl sarcosines and/or sodium *N*-acyl sarcosinates.

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### ENVIRONMENTAL PROTECTION AGENCY

[FRL-7378-9]

#### Notice of Availability of National Pollutant Discharge Elimination System (NPDES) Storm Water General Permit for Small MS4s

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of Availability of Proposed NPDES General Permit.

**SUMMARY:** The Regional Administrator, EPA, Region 9 is proposing to issue an NPDES general permit for storm water discharges from small municipal separate storm sewer systems (MS4s) located in the geographic areas of Region 9 where the NPDES permit program has not been delegated. These areas include the State of Arizona (including Indian lands), Indian lands in the States of California and Nevada, and the U.S. Pacific Island territories. For the State of Arizona (excluding Indian Country lands), the general permit is being proposed jointly by Region 9 and the Director of the Arizona Department of Environmental Quality (ADEQ). NPDES permit coverage for these discharges is required in accordance with the 1987 Amendments to the Clean Water Act (CWA), and final EPA regulations for Phase II storm water discharges (64 FR 68722, December 8, 1999). This Notice announces the availability of the proposed general permit and fact sheet for public comment.

**DATES:** *Comments:* Comments on the proposed general permit must be received or postmarked no later than October 30, 2002. Within the comment period, interested persons may also request a public hearing pursuant to 40

CFR 124.12 concerning the proposed permit.

*Public Meeting:* The public meeting will be held on October 16, 2002 at 1 p.m. to 5 p.m.

**ADDRESSES:** Comments: All public comments or requests for a public hearing must be submitted to Lisa Honor, U.S. EPA, Region 9 (WTR-5), 75 Hawthorne Street, San Francisco, CA 94105. Comments or requests for a public hearing pertaining to MS4s within non-Indian Country lands in Arizona must also be sent to Karyn Moldenhauer, ADEQ, Water Permits Unit, 1110 West Washington, Phoenix, AZ 85007.

*Public Meeting:* The public meeting will be held at the Arizona Industrial Commission Auditorium, 800 West Washington, Phoenix, AZ. A public meeting will be held to provide an opportunity for Region 9 and ADEQ to discuss the proposed permit with potential permittees and other interested persons. Written, but not oral, comments for the official public record will be accepted at the public meeting.

**FOR FURTHER INFORMATION CONTACT:** For further information on the proposed general permit, contact either Eugene Bromley, EPA, Region 9 (WTR-5), 75 Hawthorne Street, San Francisco, CA 94105 (415) 972-3510, or Karyn Moldenhauer, ADEQ, Water Permits Unit, 1110 West Washington, Phoenix, AZ 85007 (602) 771-4449.

**SUPPLEMENTARY INFORMATION:** Copies of the proposed general permit and fact sheet will be provided upon request and are also available at EPA, Region 9's website at <http://www.epa.gov/region09/water>. Additional information on Phase II of the storm water program is available at EPA's national storm water website at <http://www.epa.gov/NPDES/stormwater>.

*Administrative Record:* The proposed general permit and other related documents in the administrative record are on file and may be inspected any time between 8:30 a.m. and 4 p.m., Monday through Friday, excluding legal holidays, at the following addresses: U.S. EPA, Region 9, CWA Standards and Permits Office (WTR-5), 75 Hawthorne Street, San Francisco, CA 94105-3901. Arizona Department of Environmental Quality, Water Permits Unit, 1110 West Washington, Phoenix, AZ 85007.

#### Summary of Terms and Conditions of Proposed General Permit

##### A. Discharges Covered

The proposed general permit would authorize discharges of storm water