

**FOR FURTHER INFORMATION CONTACT:**

Mark J. Palermo, Environmental Protection Specialist, Regulation Development Section, Air Programs Branch (AR-18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-6082.

**SUPPLEMENTARY INFORMATION:**

For additional information see the direct final rule published in the final rules section of this **Federal Register**.

Dated: June 23, 1999.

**Jerri-Anne Garl,**

*Acting Regional Administrator, Region 5.*

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**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 180**

[OPP-300885; FRL-6088-4]

RIN 2070-AB18

**N-Acyl sarcosines and Sodium N-acyl sarcosinates; Tolerance Exemption**

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA proposes to establish an exemption from the requirement of a tolerance for residues of *N*-acyl sarcosines [*N*-oleoyl sarcosine (CAS Reg. No. 110-25-8); *N*-stearoyl sarcosine (CAS Reg. No. 142-48-3); *N*-lauroyl sarcosine (CAS Reg. No. 97-78-9); *N*-myristoyl sarcosine (CAS Reg. No. 52558-73-3); *N*-cocoyl sarcosine mixture (CAS Reg. No. 68411-97-2); and sodium *N*-acyl sarcosinates [*N*-methyl-*N*-(1-oxo-9-octodecenyl) glycine (CAS Reg. No. 3624-77-9); *N*-methyl-*N*-(1-oxooctadecyl) glycine (CAS Reg. No. 5136-55-0); *N*-methyl-*N*-(1-oxododecyl) glycine (CAS Reg. No. 137-16-6); *N*-methyl-*N*-(1-oxotetradecyl) glycine (CAS Reg. No. 30364-51-3); and *N*-cocoyl sarcosine sodium salt mixture (CAS Reg. No. 61791-59-1)] when used as inert ingredients (surfactants) in pesticide formulations containing glyphosate. EPA is proposing this regulation on its own initiative.

**DATES:** Written comments should be submitted to EPA on or before September 7, 1999.

**ADDRESSES:** By mail, submit written comments to: Public Information and Records Integrity Branch, Information

Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, deliver comments to: Rm. 119, Crystal Mall 2, 1921 Jefferson Davis Hwy., Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epa.gov. Follow the instructions under Unit V. of this document. No Confidential Business Information (CBI) should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential 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. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice. The public docket is available for public inspection in Rm. 119 at the Virginia address given in this unit, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

**FOR FURTHER INFORMATION CONTACT:**

Amelia M. Acierto, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall 2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-8377, acierto.amelia@epa.gov.

**SUPPLEMENTARY INFORMATION:** Prior to the enactment of the Food Quality Protection Act of 1996 (FQPA), EPA proposed that exemptions from the requirement of a tolerance be established for residues of *N*-acyl sarcosines [*N*-oleoyl sarcosine, *N*-stearoyl sarcosine, *N*-lauroyl sarcosine, *N*-myristoyl sarcosine, *N*-cocoyl sarcosine mixture] and sodium *N*-acyl sarcosinates [*N*-methyl-*N*-(1-oxo-9-octodecenyl) glycine; *N*-methyl-*N*-(1-oxooctadecyl) glycine; *N*-methyl-*N*-(1-oxododecyl) glycine; *N*-methyl-*N*-(1-oxotetradecyl) glycine; and *N*-cocoyl sodium salt mixture], in response to a pesticide petition (PP 4E4417) submitted by Hampshire Chemical Company, 55 Hayden Avenue, Lexington, MA 02173 pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e). EPA published the proposed rule in the **Federal Register** of July 24,

1996 (61 FR 38423). There were no comments received in response to the proposed rule.

This document represents an EPA-initiated proposal to establish tolerance exemptions for the above noted substances to include the Agency's determination of safety for the tolerance exemptions in view of the FQPA amendments to section 408 of FFDCA. EPA is proposing this regulation on its own initiative pursuant to section 408(e)(1)(B) of FFDCA.

**I. Risk Assessment and Statutory Authority**

New section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food commodity) only if EPA determines that the tolerance is "safe." Section 408(c)(2)(A)(ii) 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." These include exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(B) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing an exemption 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."

**II. Risk Assessment and Statutory Findings**

*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  $1.59 \pm 1.08$  micromoles per liter.

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 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.

Taking into account the proposed use in glyphosate formulations, the Agency 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.

### III. Cumulative Exposure to Substances with Common Mechanism of Toxicity

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 appear to produce a toxic metabolite produced by 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.

#### A. Aggregate Risks and Determination of Safety

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, the Agency 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. The Agency has arrived at this conclusion because of the inconsequential increases in dietary exposure resulting from its use as an inert ingredient in glyphosate formulations. EPA concludes that there is a reasonable certainty of no harm from the establishment of this tolerance exemption.

FFDCA 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 pre- and post-natal toxicity and the completeness of the database 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, EPA has not used a safety factor analysis in assessing the risk of *N*-acyl sarcosines and sodium *N*-acyl sarcosinates. For the same reason, application of the additional safety factor for infants and children would not be appropriate.

#### B. Other Considerations

1. *Endocrine disruptors.* There are no reports of any estrogenic and other adverse effects to human population as a result of the use of *N*-acyl sarcosines and/or sodium *N*-acyl sarcosinates.

2. *Analytical enforcement methodology.* The Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation; therefore, the Agency has concluded that an analytical method is not required for enforcement purposes for *N*-acyl sarcosines and sodium *N*-acyl sarcosinates.

#### C. Existing Tolerances

No existing tolerances or exemptions from the requirement of a tolerance have been issued for *N*-acyl sarcosines and/or sodium *N*-acyl sarcosinates as pesticide chemicals in the United States.

#### D. International Residue Limits

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

#### E. Conclusion

Therefore, based on the information and data considered, EPA is proposing

an exemption from the requirement of a tolerance be established for residues of *N*-acyl sarcosines and sodium *N*-acyl sarcosinates when used as inert ingredients (surfactants) in pesticide formulations containing glyphosate at a concentration not to exceed 10% weight of the formulation.

### IV. Comments

Under FFDCA section 408(e)(2), EPA must provide for a public comment period before issuing a final tolerance or tolerance exemption under section 408(e)(1). The public comment period is to be for 60 days unless the Administrator for good cause finds that it is in the public interest to reduce that comment period.

### V. Public Record and Electronic Submissions

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number [OPP-300885] (including comments and data submitted electronically as described in this unit). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official rulemaking record is located at the Virginia address in ADDRESSES at the beginning of this document.

Electronic comments can be sent directly to EPA at:  
opp-docket@epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number [OPP-300885]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

### VI. Regulatory Assessment Requirements

#### A. Certain Acts and Executive Orders

This action proposes an exemption from the tolerance requirement under FFDCA section 408(e). 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).

In addition, 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 prior consultation as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require special OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions was published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

#### B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal

governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's proposed rule does not create an unfunded Federal mandate on State, local, or tribal governments. The proposed rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this proposed rule.

#### C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments "to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's proposed rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do 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: June 22, 1999.

**James Jones,**

*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:** 15 U.S.C. 321(q), 346(a) and 371.

2. By adding new § 180.1207 to read as follows:

#### **§ 180.1207 N-acyl sarconsines and sodium N-acyl sarcosinates; exemption from requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of the following substances when used as inert ingredients (surfactants) at levels not to exceed 10% in pesticide formulations containing glyphosate:

Name	CAS Reg. No.
N-acyl sarcosines.	
N-oleoyl sarcosine .....	110-25-8
N-stearoyl sarcosine .....	142-48-3
N-lauroyl sarcosine .....	97-78-9
N-myristoyl sarcosine .....	52558-73-3
N-cocoyl sarcosine mixture	68411-97-2
Sodium N-acyl sarcosinates.	
N-methyl-N-(1-oxo-9-octodecenyl) glycine .....	3624-77-9
N-methyl-N-(1-oxooctadecyl) glycine ....	5136-55-0
N-methyl-N-(1-oxododecyl) glycine .....	137-16-6
N-methyl-N-(1-oxotetradecyl) glycine ....	30364-51-3
N-cocoyl sarcosine sodium salt mixture .....	61791-59-1

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#### **FEDERAL COMMUNICATIONS COMMISSION**

#### **47 CFR Parts 27 and 73**

[WT Docket No. 99-168; FCC 99-97]

#### **Service Rules for the 746-764 and 776-794 MHz Bands and Revisions to the Commission's Rules Regarding Wireless Communications Service**

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This document proposes new service rules for commercial licensing in the 746-764 and 776-794 MHz bands