**List of Subjects in 40 CFR Part 81**

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental relations.

Dated: May 29, 1998.

**Chuck Clarke,**

*Regional Administrator, Region 10.*

For the reasons set forth in the preamble, 40 CFR part 81 is amended as follows:

## PART 81—[AMENDED]

1. The authority citation for part 81 continues to read as follows:

**Authority:** 42 U.S.C. 7401–7671q.

2. In § 81.302, the table for ''Alaska-Carbon Monoxide'' is amended for the Anchorage area by revising the entry for the Anchorage area to read as follows:

**§ 81.302 Alaska.**

* * * * *

Alaska-Carbon Monoxide

| Designated area | Designation | | Classification | |
|---|---|---|---|---|
| | Date [1] | Type | Date [1] | Type |
| * * * * | * | * | * | * |
| Anchorage Area: | | | | |
| Anchorage Election District (part) Anchorage nonattainment area boundary. | ..... | Nonattainment .. | July 13, 1998 ... | Serious. |
| * * * * | * | * | * | * |

[1] This date is November 15, 1990, unless otherwise noted.

[FR Doc. 98–15447 Filed 6–11–98; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[OPP–300672; FRL–5795–7]**

**RIN 2070–AB78**

## Phospholipid: Lyso-PE (lysophosphatidylethanolamine); Time-Limited Pesticide Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This rule establishes a time-limited tolerance for residues of the biochemical phospholipid: Lyso-PE (lysophosphatidylethanolamine) on apples, citrus, cranberries, grapes, nectarines, peaches, pears, strawberries, and tomatoes when used to promote pre-harvest and post-harvest ripening and extend the storage shelf life. J P BioRegulators, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170) requesting the time-limited tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of phospholipid. The tolerance will expire on June 1, 2001.

**DATES:** This regulation is effective June 12, 1998. Objections and requests for hearings must be received by EPA on or before August 11, 1998.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number [OPP–300672], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP ''Tolerance Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300672], must also be submitted 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, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket number [OPP-300672]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

**FOR FURTHER INFORMATION CONTACT:** By mail: Sheila A. Moats, Regulatory Action Leader, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number, and e-mail address: 9th fl., CM #2 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703) 308–1259; e-mail: moats.sheila@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** J P BioRegulators Inc., 1611 Maple Street, Middleton, Wisconsin 53562, has requested in pesticide petition (PP 7G4892) the establishment of a temporary exemption from the requirement of a tolerance for residues of the biochemical phospholipid. A notice of filing was published in the **Federal Register** on December 10, 1997 (62 FR 65077)(FRL-5749-3), and the notice announced that the comment period would end on January 11, 1998; no comments were received. This temporary exemption from the requirement of a tolerance will permit the marketing of apples, citrus, cranberries, grapes, nectarines, peaches, pears, strawberries, and tomatoes when treated in accordance with the provisions of the experimental use

permit 70515-EUP-1, which is issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (Pub. L. 95-396, 92 Stat. 819; 7 U.S.C. 136). The data submitted in the petition and all other relevant materials have been evaluated. Following in Unit II. of this preamble is a summary of EPA's findings regarding this petition as required by section 408(d) of the FFDCA, 21 U.S.C. 346a, as recently amended by the FQPA, Pub. L. 104-170.

## I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the 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 tolerance is ''safe.'' Section 408(b)(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.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance 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 performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide us in residential settings.

## II. Summary

### *A. Proposed Use Practices*

The experimental program will be conducted in the States of Arizona, California, Florida, Massachusetts, Michigan, Ohio, Washington, West Virginia and Wisconsin. Crops to be treated are apples, citrus, cranberries, grapes, nectarines, peaches, pears, strawberries, and tomatoes. Prior to use Lyso-PE (lysophosphatidylethanolamine, a specific type of phospholipid) is diluted with water to 1%, i.e., 10,000 ppm of the active ingredient Lyso-PE. Next 1 to 5 gallons of the 1% Lyso-PE solution is mixed with sufficient water to prepare 100 gallons of spray solution containing 100 to 500 ppm of active ingredient. This solution is sprayed to run-off for pre-harvest application. The pre-harvest treatment should be limited to one application only. For post-harvest treatment fruit will be dipped in the solution prepared as described above for 30 minutes, and air dry prior to storage. The rate of application for both pre and post-harvest is equivalent to 0.083-0.14 lbs of active ingredient per 100 gallons of water. The proposed experimental use program (EUP) would utilize 72/kg/year of formulated product. A maximum of 570 acres located in nine states will be treated under this EUP. Lyso-PE is intended for enhancing and ripening the shelf life of fruits.

### *B. Product Identity/Chemistry*

The active ingredient Lysophosphatidylethanolamine (Lyso-PE), is a phospholipid derived from phosphatidylethanolamine (PE) by the enzymatic removal of one fatty acid. PE is found in large quantities in egg yolk and meat. Lyso-PE is naturally present in small amounts in plant tissues and other biological matrices and can account for up to 10% of the phospholipid content of cell membranes. Lyso-PE is found in many food commodities such as human breast milk, cow milk, corn grain and starch, oats and wheat. The current analytical methodology cannot distinguish between product ingredients present in or on food commodities following application of the product, and those ingredients that are naturally present in the food commodities. Lyso-PE is a fine white powder, with a pH of 6 to 8. Its specific gravity is approximately 1g/mL.

### *C. Toxicological Profile*

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Additionally, 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.''

Waivers of data requirements for toxicology and non-target organisms were requested and information obtained from the open technical literature was used to support the request. Waivers were accepted on the basis of favorable toxicological profile, the natural occurrence of the chemical, and inconsequential exposure resulting from label-directed uses.

### *D. Aggregate Exposures*

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from groundwater or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Dietary exposure*. Dietary exposure due to topical applications of the phospholipid Lyso-PE is difficult to estimate because of its prevalence in nature; applications associated with the EUP would be minuscule compared to levels found in nature. Phospholipid in the environment is readily utilized by microorganisms. Furthermore, phospholipid is consumed by humans in the form of eggs, milk, grains etc. in relatively large quantities. The low toxicity, low application rate, and the use pattern leads the Agency to conclude that residues from the use of the phospholipid biochemical Lyso-PE will not pose a dietary risk of concern under foreseeable circumstances. Therefore, EPA concludes that there is a reasonable certainness of no harm from aggregate exposure under this temporary exemption.

2. *Non-dietary, non-occupational exposure*. Increased non-dietary exposure to Lyso-PE via lawn care, topical insect repellents, etc., is not applicable to this EUP.

### *E. Cumulative Exposure to Substances with Common Mechanisms 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.''

Phospholipid is ubiquitous in nature. Incremental exposure resulting from this EUP program are minuscule when compared to the levels found naturally-occurring in food.

### *F. Safety Factors*

Phospholipid is naturally occurring in food and is present in all cells in all organisms. Incremental exposure to

phospholipid resulting from this EUP is minuscule. Considering the negligible contributions to the environment resulting from the application of Lyso-PE, the abundance and role of phospholipid in foods and in cells of all living organisms and its prevalence in nature, the Agency concludes that the application of Lyso-PE to the aforementioned crops does not pose a dietary risk.

## III. Other Considerations

### *A. Endocrine Disruptors*

The Agency has no information to suggest that Lyso-PE will adversely affect the immune or endocrine systems. The Agency is not requiring information on the endocrine effects of this biochemical pesticide at this time; Congress had allowed three years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects.

### *B. Analytical Method*

An analytical method using High Performance Liquid Chromatography (HPLC/ELSD) for determining phospholipid content in Lyso-PE the end-use product, is available; however, because this phospholipid is found naturally in cells of all organisms, the Agency has determined that residue analysis would not yield meaningful results, i.e.,the analysis would not discern whether the source of phospholipid was from cells of organisms or the product treatment.

### *C. Codex Maximum Residue Level*

There are no CODEX tolerances or international tolerance exemptions for Lyso-Pe at this time.

## IV. Conclusion

Based on its abundance in nature and long history of use by humans without deleterious effects, there is reasonable certainty that no harm will result from aggregate exposure to the U.S. population, including infants and children, to residues of Lyso-PE. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion because, as discussed above, exposure to Lyso-PE resulting from the EUP label-directed use is inconsequential, and it is consumed daily by the human population from both naturally-occurring sources and from processed foods. As a result, EPA establishes a temporary exemption from the requirement of a tolerance pursuant to FFDCA section 408(j)(3) for Lyso-PE (lysophosphatidylethanolamine) on the condition that it be used in accordance with the experimental use permit 70515-EUP-1, with the following provisions:

1. The total amount of the active ingredients to be used must not exceed the quantity authorized by the experimental use permits.

2. J P BioRegulators, Inc., must immediately notify the EPA of any findings from the experimental use that have a bearing on safety. The company must also keep records of production, distribution, and performance and on request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration (FDA).

This temporary exemption from the requirement of a tolerance expires and is revoked on June 1, 2001. Residues remaining in or on the raw agricultural commodity after this expiration date will not be considered actionable if the biochemical is legally applied during the term of, and in accordance with, the provisions of the amended experimental use permit and temporary exemption from the requirement of a tolerance. This temporary exemption from the requirement of a tolerance may be revoked if the experimental use permit is revoked or if any experience with or scientific data on this pesticide indicate that the tolerance is not safe.

EPA will publish a document in the **Federal Register** to remove the revoked temporary exemption from the Code of Federal Regulations.

## V. Objections and Hearing Requests

The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d)and as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by August 11, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the hearing clerk, at the address given under the ''Addresses'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the hearing clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request 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 information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

## VI. Public Record and Electronic Submissions

A record has been established for this rulemaking under docket control number [OPP–300672]. A public version of this record, 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 public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division(7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public

version, as described above, is kept in paper form. Accordingly, in the event there are objections and hearing request, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record. The official rulemaking record is the paper record maintained at the Virginia address in Addresses at the beginning of this document.

## VII. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA 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). This final 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) (Pub.L. 104-4). Nor does it require and 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 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 additions, since tolerance 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. Nevertheless, 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 published on May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

## VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. 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 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: June 3, 1998.

**Marcia E. Mulkey,**

*Director, 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. 346a and 371.

2. Section 180.1199 is added to subpart D to read as follows:

### § 180.1199 Phospholipid: Lyso-PE (lysophosphatidylethanolamine); temporary exemption from the requirement of a tolerance.

The phospholipid biochemical Lyso-PE (lysophosphatidylethanolamine); is temporarily exempted from the requirement of a tolerance for residues when used on crops including: apples, citrus, cranberries, grapes, nectarines, peaches, pears, strawberries, and tomatoes. This temporary exemption from the requirement of a tolerance will permit the marketing of the food commodities in this paragraph when treated in accordance with the provisions of experimental use permit 70515-EUP-1, which is being issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136). This temporary exemption from the requirement of a tolerance expires and is revoked on June 1, 2001. This temporary exemption from the requirement of a tolerance may be revoked at any time if the experimental use permit is revoked or if any experience with or scientific data on this pesticide indicate that the tolerance is not safe.

[FR Doc. 98–15597 Filed 6–11–98; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 180

**[OPP–300670; FRL–5795–3]**

**RIN 2070–AB78**

## Propamocarb hydrochloride; Extension of Tolerances for Emergency Exemptions

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

**ACTION:** Final rule.

**SUMMARY:** This rule extends time-limited tolerances for residues of the fungicide propamocarb hydrochloride in or on potatoes at 0.5 part per million (ppm); fat, meat, meatbyproducts (except kidney and liver) of cattle, goats, hogs, horses, and sheep; and milk at 0.1 ppm; and tomatoes at 0.5 ppm; tomato paste at 3 ppm; and tomato puree at 1 ppm for an additional year and a half. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on potatoes and tomatoes. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA.

**DATES:** This regulation becomes effective June 12, 1998. Objections and requests for hearings must be received by EPA, on or before August 11, 1998.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number, [OPP–300670], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations