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. Offer alternative ways to improve the notice.

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

8. To ensure proper receipt by EPA, be sure to identify the docket control 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?

The Agency is taking the action of advertising the efforts of the Non-Dietary Exposure Task Force, in the event interested parties would like to become part of the Task Force.

List of Subjects

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

Dated: August 4, 2000.

Joseph J. Merenda,

Acting Director, Office of Pesticide Programs.

[FR Doc. 00–21920 Filed 8–29–00; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–956; FRL–6595–5]

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 control number PF–956, must be received on or before September 29, 2000.

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 control number PF–956 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Indira Gairola, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–6379; e-mail address: gairola.indira@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'' 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 control number PF–956. 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 control number PF–956 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,''* 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 control

number PF–956. 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 control 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 Comestic 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: August 15, 2000.

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 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.

International Specialty Products

6E4728

EPA has received a pesticide petition PP 6E4728 from International Specialty Products, 1361 Alps Road, Wayne, NJ 07470 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for *N* (n-octyl)-2-pyrrolidone (Agsolex 8®) and *N*-(n-dodecyl)-2-pyrrolidone (Agsolex 12®) when used as an inert ingredient in or on growing crops, when applied to raw agricultural commodities, or to animals (40 CFR 180.1001(c) and (e)). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; 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.

A. Residue Chemistry

Plant metabolism. The Agency does not generally require residue chemistry data or environmental fate data to rule on the exemption from the requirement of a tolerance for an inert ingredient. However, relevant dietary residue modeling as well as extensive environmental fate data has been completed.

B. Toxicological Profile

1. *Acute toxicity*—i. *N-(n-octyl)-2-pyrrolidone.* The acute oral LD_{50} for *N*-(n-octyl)-2-pyrrolidone when tested as sold, was found to be 2.05 grams/kilograms bodyweight (g/kg bwt). Graded dose levels (0.63–5.00 g/kg) of *N*-(n-octyl)-2-pyrrolidone were administered to five groups of fasted Wistar-strain albino rats (5 male, 5 female per group). The animals were observed for pharmacological effects, external signs of toxicity, and mortality over a 14–day period.

ii. *N-(n-dodecyl)-2-pyrrolidone.* The acute oral LD_{50} for *N*-(n-dodecyl)-2-pyrrolidone, when tested as supplied, was found to be greater than 5 g/kg bwt. A single dose level of *N*-(n-dodecyl)-2-pyrrolidone was administered to 10 fasted Wistar-strain albino rats (5 male, 5 female). The animals were observed for external signs of toxicity or pharmacological effects and mortality over a 14–day period.

2. *Primary ocular irritation*—i. *N-(n-octyl)-2-pyrrolidone. N*-(n-octyl)-2-pyrrolidone was found to be extremely irritating when tested as sold, with wash procedures reducing the severity of the irritation observed. The 2% aqueous suspension was nonirritating both with and without washout procedures. Nine New Zealand white rabbits each received a single intra-ocular application of 0.1 mL of *N*-(n-octyl)-2-pyrrolidone tested as sold. An additional 9 animals received a single application of a 2% aqueous suspension of *N*-(n-octyl)-2-pyrrolidone. In both assays, the eyes of 6 animals remained unwashed for 24 hours while the eyes of the remaining 3 animals were washed 30 seconds after instillation of the test materials. Observations of ocular irritation were recorded 24, 48, and 72 hours following instillation of test materials. Additional readings were made at 4, 7, 14, and 21 days in the assay where *N*-(n-octyl)-2-pyrrolidone was tested as sold. The eyes were scored for corneal opacity, iritis, conjunctivitis and other effects.

ii. *N-(n-dodecyl)-2-pyrrolidone. N*-(n-dodecyl)-2-pyrrolidone when tested as sold was considered moderately irritating to rabbit eyes, with wash procedures reducing both the severity and duration of the irritation observed. The 2% aqueous suspension was nonirritating both with and without washout procedures. Nine New Zealand white rabbits each received a single intraocular application of 0.1 mL of *N*-(n-dodecyl)-2-pyrrolidone tested as sold. An additional 9 animals received a

single application of a 2% aqueous suspension of *N*-(n-dodecyl)-2-pyrrolidone. In both assays, the eyes of 6 animals remained unwashed for 24 hours while the eyes of the remaining 3 animals were washed 30 seconds after instillation of the test materials. Observations for ocular irritation were recorded 24, 48, and 72 hours following instillation of test materials. Additional readings were made at 4, 7, 14, and 21 days in the assay where *N*-(n-dodecyl)-2-pyrrolidone was tested as sold. The eyes were scored for corneal opacity, iritis, conjunctivitis and other effects.

3. *Primary dermal irritation*—i. *N-(n-octyl)-2-pyrrolidone*. *N*-(n-octyl)-2-pyrrolidone was extremely irritating to rabbit skin when tested as sold, and minimally irritating as a 2% suspension. The backs of 6 New Zealand white rabbits were closely clipped and the skin on the right side was abraded by making longitudinal epidermal incisions. The skin on the left side was left intact. A single application of 0.5 mL of *N*-(n-octyl)-2-pyrrolidone, tested as sold, was made to each test site. In a second assay, an additional 6 rabbits received single applications of a 2% aqueous suspension of *N*-(n-octyl)-2-pyrrolidone. In both assays, the wrapping and compound were removed at 24 hours and the sites scored at 24 and 72 hours for erythema and edema using the Draize scale. The mean scores at 24 and 72 hours were averaged to yield a primary irritation index of 7.45 for *N*-(n-octyl)-2-pyrrolidone, when tested as sold, and 0.50 when tested as a 2% gravimetric aqueous suspension.

ii. *N-(n-dodecyl)-2-pyrrolidone*. *N*-(n-dodecyl)-2-pyrrolidone was severely irritating to rabbit skin when tested as sold, and mildly irritating as a 2% suspension. The backs of 6 New Zealand white rabbits were closely clipped and the skin on the right side was abraded by making longitudinal epidermal incisions. The skin on the left side was left intact. A single application of 0.5 mL of *N*-(n-dodecyl)-2-pyrrolidone, tested as sold, was made to each test site. In a second assay, an additional 6 rabbits received single applications of a 2% aqueous suspension of *N*-(n-dodecyl)-2-pyrrolidone. In both assays, the wrapping and compound were removed at 24 hours and the sites scored at 24 and 72 hours for erythema and edema using the Draize scale. The mean scores at 24 and 72 hours were averaged to yield a Primary Irritation Index of 6.5 for *N*-(n-dodecyl)-2-pyrrolidone, when tested as sold, and 1.28 when tested as a 2% gravimetric aqueous suspension.

4. *Acute dermal toxicity*—i. *N-(n-octyl)-2-pyrrolidone*. The acute dermal LD_{50} for *N*-(n-octyl)-2-pyrrolidone when tested undiluted was determined to be greater than 2 g/kg bwt. Six New Zealand white rabbits each received a single dermal application of undiluted N-(n-octyl)-2-pyrrolidone at a dose level of 2 g/kg bwt. The skin of 3 animals was abraded, while the remaining animals skin remained intact. Test sites were occluded for 24 hours at which time the occlusive wrap and any remaining test article were removed. Animals were observed for pharmacologic activity 1, 3, 6, and 24 hours after treatment and daily thereafter for a total of 14 days. A gross necropsy was performed on all animals. The skin at the test sites showed crust formation, scaling and scarring. No gross internal changes were observed in any of the animals.

ii. *N-(n-dodecyl)-2-pyrrolidone*. The acute dermal LD_{50} for *N*-(n-dodecyl)-2-pyrrolidone, when tested undiluted, was determined to be greater than 2 g/kg bwt. Six New Zealand white rabbits each received a single dermal application of *N*-(n-dodecyl)-2-pyrrolidone at a dose level of 2 g/kg bwt. The skin of 3 animals was abraded, while the remaining animals' skin remained intact. Test sites were occluded for 24 hours at which time the wrap and any remaining test article were removed. Animals were observed for pharmacologic activity 1, 3, 6, and 24 hours after treatment and daily thereafter for a total of 14 days. A gross necropsy was performed on all animals. The skin at the test sites was moderately to severely reddened, with crust formation, scarring, and scaling observed. No gross internal changes were observed in 5 of the 6 animals. One female animal died on day 5 of the observation period.

5. *Department of Transportation corrosivity*—i. *N-(n-octyl)-2-pyrrolidone*. *N*-(n-octyl)-2-pyrrolidone when tested as sold, was found to be corrosive to the skin of rabbits under conditions of this test. Six New Zealand white rabbits each received a single dermal application of 0.5 mL of undiluted *N*-(n-octyl)-2-pyrrolidone on 1 intact test site. The test site was occluded for 4 hours at which time the occlusive wrap and any remaining material were removed. Animals were observed for erythema, edema, and other effects at 4, 48, hours, and 7 days after application. Crust formation was observed in 5 of the 6 animals.

ii. *N-(n-dodecyl)-2-pyrrolidone*. *N*-(n-dodecyl)-2-pyrrolidone, when tested undiluted, was found to be corrosive to rabbit skin under the conditions of this test. Six New Zealand white rabbits each received a single dermal application of 0.5 mL *N*-(n-dodecyl)-2-pyrrolidone on 1 intact test site. The test site was occluded for 4 hours at which time the occlusive wrap and any remaining test material were removed. The animals were observed for erythema, edema, and other effects at 4, 48, hours, and 7 days after application. Crust formation was seen in 5 of 6 animals at day 7.

6. *Guinea pig sensitization study*—i. *N-(n-octyl)-2-pyrrolidone*. In the screening test described below, *N*-(n-octyl)-2-pyrrolidone produced evidence of delayed contact hypersensitivity in 2 of the 20 test animals. Twenty female albino guinea pigs received intradermal injections of 0.05% v/v *N*-(n-octyl)-2-pyrrolidone in both water and in Freund's complete adjuvant (FCA) as well as FCA in water alone. One week after the injections, the same interscapular area was covered occlusively for 48 hours with a patch saturated with *N*-(n-octyl)-2-pyrrolidone 30% v/v in distilled water. During this induction phase, 10 control animals were treated similarly with the exception that the test material was omitted from the injections and topical applications. Two weeks after the induction period, both the test and control animals were challenged topically using a patch saturated in 0.2 mL *N*-(n-octyl)-2-pyrrolidone, 10% v/v in distilled water applied to an anterior site on the flank and *N*-(n-octyl)-2-pyrrolidone, 5% v/v in distilled water applied in a similar manner to a posterior site. The patches were sealed to the flank covered for 24 hours. The challenge sites were evaluated at 24, 48, and 72 hours after patch removal.

ii. *N-(n-dodecyl)-2-pyrrolidone*. In the screening test described below, *N*-(n-dodecyl)-2-pyrrolidone produced evidence of delayed contact hypersensitivity. Twenty female albino guinea pigs received intradermal injections of 0.05% v/v *N*-(n-dodecyl)-2-pyrrolidone in both water and in FCA as well as FCA in water alone. One week after the injections, the same interscapular area was covered occlusively for 48 hours with a patch saturated with *N*-(n-dodecyl)-2-pyrrolidone, 2.5% v/v in distilled water. During this induction phase, 10 control animals were similarly treated with the exception that the test material was omitted from the injections and topical applications. Two weeks after the induction period, both the test and control animals were challenged topically using a patch saturated in 0.2 mL *N*-(n-dodecyl)-2-pyrrolidone, 1% v/v in distilled water applied to an anterior site on the flank and *N*-(n-dodecyl)-2-pyrrolidone, 0.5% v/v in distilled water applied in a similar

manner to a posterior site. The patches were sealed to the flank and covered for 24 hours. The challenge sites were evaluated at 24, 48, and 72 hours after patch removal. Evidence of delayed contact sensitivity was produced by *N*-(n-dodecyl)-2-pyrrolidone in 5 animals. An inconclusive response was seen in 2 animals.

7. *Clinical studies*—i. *N-(n-octyl)-2-pyrrolidone*. *N*-(n-octyl)-2-pyrrolidone did not induce contact dermal phototoxic response, contact dermal photoallergy or contact dermal sensitization in human subjects under conditions of the following tests.

ii. *N-(n-dodecyl)-2-pyrrolidone*. *N*-(n-dodecyl)-2-pyrrolidone did not induce contact dermal phototoxic response, contact dermal photoallergy or contact dermal sensitization in human subjects under conditions of the following tests.

8. *Phototoxicity*—i. *N-(n-octyl)-2-pyrrolidone*. Each of 10 human subjects, all females, received 0.2 mL of a 1% suspension of test material in tap water on both volar forearms. Following a 24–hour exposure period under occlusive wrapping, the patches were removed and the sites scored for erythema and edema. Immediately following scoring, 1 arm was irradiated with ultraviolet (UV)-A light. Test sites were scored immediately after irradiation and again at 24 and 48 hours. The nonirradiated arm served as a control. No reactions were exhibited on either the irradiated or nonirradiated sites. *N*-(n-octyl)-2-pyrrolidone did not induce contact dermal phototoxic response in human subjects under conditions of this test.

ii. *N-(n-dodecyl)-2-pyrrolidone*. Each of 10 human subjects, all females, received 0.2 mL of a 1% suspension of test material in tap water on both volar forearms. Following a 24–hour exposure period under occlusive wrapping, the patches were removed and the sites scored for erythema and edema. Immediately following scoring, 1 arm was irradiated with UV-A light. Test sites were scored immediately after irradiation and again at 24 and 48 hours. The nonirradiated arm served as a control. One subject exhibited a faint, minimal reaction to the test material before and after irradiation. *N*-(n-dodecyl)-2-pyrrolidone did not induce contact dermal phototoxic response under conditions of this test.

9. *Photoallergy*—i. *N-(n-octyl)-2-pyrrolidone*. Each of 25 human subjects, 6 males and 19 females, received 0.2 mL of a 1% suspension of test material in tap water on both volar forearms. Following a 24–hour exposure period under occlusive wrapping, the patches were removed and the sites scored for erythema and edema. Immediately after scoring, 1 arm was irradiated with both UV-A and UV-B light. The UV-A exposure period was 15 minutes; the UV-B exposure period was adjusted based on each subject's skin type minimal erythema dose. Sites were scored immediately following irradiation. A series of 6 induction patches was applied twice a week for 3 weeks. Following a 2–week rest period, challenge patches were applied to virgin sites on each forearm. After a 24–hour exposure period, both sites were scored and the previously designated arm was irradiated. The sites were scored immediately after irradiation and again at 24 and 48 hours. During the induction phase, 5 subjects exhibited a faint, minimal reaction on the irradiated contact site and one subject exhibited erythema and/or slight edema on the nonirradiated site. No reactions were exhibited at the challenge phase. *N*-(n-octyl)-2-pyrrolidone did not induce contact dermal photoallergy nor contact dermal sensitization under conditions of this test.

ii. *N-(n-dodecyl)-2-pyrrolidone*. Each of 25 human subjects, 6 males and 19 females, received 0.2 mL of a 1% suspension of test material in tap water on both volar forearms. Following a 24–hour exposure period under occlusive wrapping, the patches were removed and the sites scored for erythema and edema. Immediately after scoring, 1 arm was irradiated with UV-A and UV-B light. The UV-A exposure period was 15 minutes; the UV-B exposure period was adjusted based on each subject's skin type minimal erythema dose. Sites were scored immediately following irradiation. A series of 6 induction patches was applied twice a week for 3 weeks. Following a 2–week rest period, challenge patches were applied to virgin sites on each forearm. After a 24–hour exposure period, both sites were scored and the previously designated arm was irradiated. The sites were scored immediately after irradiation and again 24 and 48 hours. During the induction phase, 9 subjects exhibited a faint, minimal reaction at the irradiated contact site and 4 subjects exhibited a similar reaction at the non-irradiated contact site. No reactions were exhibited at the challenge phase. *N*-(n-dodecyl)-2-pyrrolidone induced neither contact dermal photoallergy nor contact dermal sensitization under conditions described.

10. *Repeated insult patch test*—i. *N-(n-octyl)-2-pyrrolidone*. Each of 100 human subjects, 26 males and 74 females, received 0.2 mL of a 1% suspension of test material in tap water on the left upper back area. Following a 24–hour exposure period under occlusive wrapping, the patches were removed and scored for erythema and edema. A series of 9 induction phases was applied 3 times a week for 3 weeks. Following a 2–week rest period, challenge patches were applied to a virgin site on the right upper back area and allowed to remain in skin contact for 24 hours. Challenge sites were scored for erythema and edema at 24, 48, and 72 hours post-patching. During the induction phase, 61 subjects exhibited slight reactions; several subjects exhibited hyperpigmentation and/or dryness. The induction patch sites exhibited no reactions during the rest period or at the challenge. During the challenge phase, 3 subjects exhibited a faint, minimal reaction at the challenge site. After repeated applications under conditions of this test, *N*-(n-octyl)-2-pyrrolidone did not induce contact dermal sensitization.

ii. *N-(n-dodecyl)-2-pyrrolidone*. Each of 100 human subjects, 26 males and 74 females, received 0.2 mL of a 1% suspension of test material in tap water on the left upper back area. Following a 24–hour exposure period under occlusive wrapping, the patches were removed and scored for erythema and edema. A series of 9 induction patches was applied 3 times a week for 3 weeks. Following a 2–week rest period, challenge patches were applied to a virgin site on the right upper back area and allowed to remain in skin contact for 24 hours. Challenge sites were scored for erythema and edema at 24, 48, and 72 hours post-patching. During the induction phase, 50 subjects exhibited slight reactions, several subjects exhibited hyperpigmentation and/or dryness. The induction patch sites exhibited no reactions during the rest period or at the challenge. During the challenge phase, 12 subjects exhibited faint, minimal reactions at the challenge site, 1 exhibited dryness. After repeated applications under conditions of this test, *N*-(n-dodecyl)-2-pyrrolidone did not induce contact dermal sensitization.

11. *Comodogenicity*—i. *N-(n-octyl)-2-pyrrolidone*. Under conditions of this study, in which a mean comedogenic grade of ≥2.0 in rabbits is considered to indicate potential comedogenesis in humans, *N*-(n-octyl)-2-pyrrolidone is not expected to be comedogenic in humans. The comedogenicity potential of *N*-(n-octyl)-2-pyrrolidone was assessed in New Zealand white rabbits. The external ear canal of 6 animals received dermal application of 0.5 mL of 2% *N*-(n-octyl)-2-pyrrolidone in distilled water, 5 days a week over a 4–week period. Microscopic examination of the treated tissues was then

performed. Minimal to moderate local irritation was noted in all test animals characterized by redness, eschar, dryness, and flaking. A mild to moderate comedogenic response was observed in 4 of the treated rabbits each receiving a comedogenic grade of 1.0 on a scale of 0 to 5. The remaining test animals received a grade of 0 (negative), yielding a mean comedogenic grade of 0.67. There were no neoplastic microscopic findings in this study.

ii. *N-(n-dodecyl)-2-pyrrolidone*. Under conditions of this study, in which a mean comedogenic grade of ≥2.0 in rabbits is considered to indicate potential comedogenesis in humans, *N*-(n-dodecyl)-2-pyrrolidone is not expected to be comedogenic in humans. The comedogenicity potential of *N*-(n-dodecyl)-2-pyrrolidone was assessed in New Zealand white rabbits. The external ear canal of 6 animals received dermal applications of 0.5 mL of 2% *N*-(n-dodecyl)-2-pyrrolidone in distilled water, 5 days a week over a 4–week period. Microscopic examination of the treated tissue was then performed. Minimal to moderate local irritation was noted in all test animals characterized by redness, eschar, dryness, and flaking. A mild to moderate comedogenic response was observed in 1 of the treated rabbits receiving a comedogenic grade of 3 on a scale of 0 to 5. The remaining test animals received a grade of 0 (negative), yielding a mean comedogenic grade of 0.5. There were no neoplastic microscopic findings.

12. *Ames Salmonella/microsome reverse mutation assay*—i. *N-(n-octyl)-2-pyrrolidone*. No mutagenic activity was demonstrated by *N*-(n-octyl)-2-pyrrolidone when tested as sold in the Ames assay. *N*-(n-octyl)-2-pyrrolidone was tested, as sold, in the Ames assay with *Salmonella typhimurium* tester strains TA 1535, TA 1537, TA 1538, TA 98, and TA 100. Tests were conducted in all 5 strains both with and without metabolic activation (induced S–9 rat liver preparation). The entire assay was performed twice.

ii. *N-(n-dodecyl)-2-pyrrolidone*. No mutagenic activity was demonstrated for *N*-(n-dodecyl)-2-pyrrolidone in the Ames *Salmonella*/microsome reverse mutation assay. *N*-(n-dodecyl)-2-pyrrolidone was tested, as sold, in the Ames assay with *Salmonella typhimurium* tester strains TA-1535, TA-1537, TA-1538, TA-98, and TA-100. Tests were conducted in all 5 strains both with and without metabolic activation (induced S–9 rat liver preparation). The results from the initial assay were confirmed in an independent assay.

13. *Mouse micronucleas test*—i. *N-(n-octyl)-2-pyrrolidone*. *N*-(n-octyl)-2-pyrrolidone was found to be non-mutagenic at a dose level of 1,720 mg/kg in this *in vivo* cytogenetic test. Mice were administered *N*-(n-octyl)-2-pyrrolidone by intragastric gavage at a dose level of 1,720 mg/kg, based on results of a preliminary toxicity test. Controls were dosed in the same manner. Bone marrow smears were obtained at 24, 48, and 72 hours post-dosing and examined for the presence of micronuclei in polychromatic and normochromatic erythrocytes. The ratio of polychromatic to normochromatic erythrocytes (P/N ratio) was also assessed. At sampling times mice treated with *N*-(n- octyl)-2-pyrrolidone showed no significant increase in frequency of micronucleated polychromatic erythrocytes, nor was there a significant decrease in P/N ratio at any of the sampling times.

ii. *N-(n-dodecyl)-2-pyrrolidone*. *N*-(n-dodecyl)-2-pyrrolidone was found to be non-mutagenic at a dose level of 5,000 mg/kg in this *in vivo* cytogenetic test. Mice were administered *N*-(n-dodecyl)-2-pyrrolidone by intragastric gavage at a dose level of 5,000 mg/kg, based on results of a preliminary toxicity test. Vehicle controls were dosed with corn oil in the same manner. Bone marrow smears were obtained at 24, 48, and 72 hours post-dosing and examined for the presence of micronuclei in polychromatic and normochromatic erythrocytes. The ratio of polychromatic to normochromatic erythrocytes (P/N ratio) was also assessed. At sampling times, mice treated with *N*-(n-dodecyl)-2-pyrrolidone showed no significant increase in frequency of micronucleated polychromatic erythrocytes. There was, however, a statistically significant decrease in P/N ratio at 24 and 72 hour sampling times which may be indicative of bone marrow cell depression/toxicity.

14. *Mouse lymphoma mutagenesis assay*. The results of this assay indicate that *N*-(n-octyl)-2-pyrrolidone produced a negative response in cultures treated in either the absence of exogenous activation or the presence of Aroclor-induced rat liver S–9 mix. In this assay, *N*-(n-octyl)-2-pyrrolidone was tested for its potential to induce mutations at the thymidine Kinase locus of L5128Y TK+/-mouse lymphoma cells both in the presence and absence of exogenous metabolic activation. Based on the results of a range finding test the test article was tested in the assay at doses ranging 0.005 to 100 uL/mL which produced varying degrees of reduction in cell growth.

15. *Reproductive and developmental toxicity*. *N*-(n-octyl)-2-pyrrolidone was administered orally by gavage, once daily, to pregnant female Wistar rats from day 6 through day 15 post coitum, at dosages of 50, 200, or 800 mg/kg bwt/day in order to assess the effects on embryonic and fetal development. At 800 mg/kg/day, 1 dam died after the 7th and 1 after the 10th test article administration. The females of this group had marked clinical signs of reaction to treatment, reduced food consumption, slight body weight loss during the first day of dosing and reduced corrected body weight gain. The mean fetal body weight was reduced at this dosage, combined with a delay of skeletal ossification. At 50 or 200 mg/kg/day, no effects of treatment with the test article on maternal or fetal parameters were evident. Based on the results of this study, the no observed adverse effect level (NOAEL) for the maternal and fetal parameters was considered to be 200 mg/kg bwt/day. *N*-(n-octyl)-2-pyrrolidone did not reveal any teratogenic potential up to and including the highest dose tested (HDT) level of 800 mg/kg bwt/day when administered to pregnant Wistar rats under the conditions described for this study.

16. *28–Day oral toxicity*—i. *N-(n-octyl)-2-pyrrolidone*. In a 28–day oral toxicity study in rats, the no-effect level of *N*-(n-octyl)-2-pyrrolidone was determined to be 55 mg/kg/day. At 320 mg/kg/day specific changes in general health, body weight gain, hematological and biochemical parameters were recorded. *N*-(n-octyl)-2-pyrrolidone, formulated as a solution in corn oil, was administered to rats (5 males, 5 females per dosage level) by intragastric intubation at dosage levels of 5, 55, or 320 mg/kg/day. Treatment was carried out once daily for 28 consecutive days. Similarly, control animals received corn oil (5 mL/kg/day) included: Statistically significant observations noted at the high dose level of 320 mg/kg day included: Lower body weight gains in females (week 3); lower packed cell volume (PCV) and red blood cell counts in males, corpuscular hemoglobin concentration (MCHC) in males; and higher glutamic-pyruvic transaminase levels in females. In all other respects including food consumption, organ weights, macroscopic and microscopic pathology, no changes were noted that were considered to be treatment-related.

ii. *N-(n-dodecyl)-2-pyrrolidone*. In a 28–day oral toxicity study in rats, the no-effect level of *N*-(n-dodecyl)-2-pyrrolidone was determined to be 100 mg/kg/day. *N*-(n-dodecyl)-2-pyrrolidone, formulated as a solution in corn oil, was administered to rats (5 males, 5 females per dosage level) by

intragastric intubation at dosage levels of 10, 100, or 1,000 mg/kg/day. Treatment was carried out once daily for 28 consecutive days. Similarly, control animals received corn oil (5 mL/kg/day). At 1,000 mg/kg/day specific changes in general health, body weight gains, food consumption, biochemical parameters, organ weights, macroscopic and microscopic pathology were recorded. Statistically significant observations noted at the high dose level of 1,000 mg/kg/day included: Lower food consumption and bodyweight gains in males; higher glutamic-pyruvic transaminase levels in males and females; higher blood urea nitrogen levels in females; and higher adjusted liver weights in females, and minimal centrilobular hepatocyte enlargement in males and females.

17. *90–Day oral toxicity in dogs*. In a 90–day oral toxicity study in dogs, a dose level of 30 mg/kg/day was determined to be the NOAEL. *N*-(n-octyl)-2-pyrrolidone was administered orally via capsule at dosage levels of 30, 90, and 240 mg/kg/day. All animals were observed daily for clinical signs of toxicity. After treatment, all surviving animals were subjected to complete necropsy with histological examination. Dose related neurological signs and body weight loss were observed at 90 and 240 mg/kg/day levels. Also at 90 and 240 mg/kg/day, changes in clinical pathological parameters were observed and were dose-related. In addition, dose-related increases in both absolute and relative liver weights were observed in all groups but was significant in only 90 and 240 mg/kg/day groups. One female death occurred on day 42 in the 240 mg/kg/day group.

18. *90–Day dietary toxicity in rats*. Based on the results of a 90–day feeding study in rats, 600 parts per million (ppm) was considered a NOAEL following dietary administration of *N*-(n-octyl)-2-pyrrolidone for 90 days. *N*-(n-octyl)-2-pyrrolidone was administered orally via diet to rats at dosage levels of 60, 600, and 10,000 ppm. All animals were observed daily for clinical signs of toxicity. After treatment, all surviving animals were subjected to complete necropsy with histological examination. Reduced weight gain, increased absolute and relative liver weights and mild hepatocyte hypertrophy were observed at 10,000 ppm. No treatment-related effects were observed at 60 and 600 ppm.

19. *Endocrine disruption*. *N*-(n-octyl)-2-pyrrolidone and *N*-(n-dodecyl)-2-pyrrolidone are not expected to be endocrine disrupters. They do not share structural similarity with currently known or suspected chemicals or chemical classes being studied for this effect.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Residue data are generally not required for inert ingredient exemptions from a tolerance. International Specialty Products has exposure data on 4 representative crops to support the listing of *N*-(n-octyl)-2-pyrroidone and *N*-(n-dodecyl)-2-pyrrolidone as an inert ingredient exempted from the requirements of a tolerance when used in accordance with good agricultural practices at levels not to exceed 1% in the final solution for preharvest and postharvest application, and application to animals. A dietary residue exposure system (DRES) analysis was run using a model based on Kenaga and Hoerger's ''Maximum Expected Residues on Vegetation.'' The four representative crops chosen for the analysis were: Wheat, lettuce, apples, and sugar beets. The reference dose used by EPA, was derived from the NOAEL obtained from an animal study in dogs, the most sensitive species in chronic studies with these materials. For *N*-(n-octyl)-2-pyrrolidone the NOAEL was 30 mg/kg bwt/day in the 90–day dog study. A 250–fold safety factor results in a reference dose of 0.12 mg/kg bwt/day. This reference dose (RfD) can then be compared to the dietary exposure yielding a ''percent of dose utilized'' estimate. An application rate of 0.25 lb (113 grams) *N*-(n-octyl)-2-pyrrolidone and *N*-(n-dodecyl)-2-pyrrolidone/acre of crop was used for the analysis. Apples, under the category of ''fruit-cherries, peaches'' results in an estimated residue of 1.75 ppm. Lettuce (head and leaf), under the category ''leaves and leafy crops'' results in an estimated residue of 31 ppm. Wheat, under the category of ''forage-alfalfa, clover'' results in an estimated residue of 14 ppm. Sugar beets (root crop) is not estimated in the model, but a default value of 5 ppm is assumed. This is a conservative estimate given that the pesticide formulation does not physically touch the crop.

Using these input parameters, a residue file was assembled which lists the chronic reference dose and all of the relevant commodities that are included in the consumption data base. The exposure analysis shows that, for the U.S. population (general population, 48 contiguous states, all seasons), the listed crops utilize only 25% of the reference dose. This analysis shows there is a substantial margin of safety for the use of *N*-(n-octyl)-2-pyrrolidone and *N*-(n-dodecyl)-2-pyrrolidone on these crops at 0.25 lb/acre.

ii. *Drinking water*. Based on its very low application rate, as well as the environmental fate studies, *N*-(n-octyl)-2-pyrrolidone and *N*-(n-dodecyl)-2-pyrrolidone would not be expected to persist in the environment, nor contaminate drinking water supplies.

2. *Non-dietary exposure*. *N*-(n-octyl)-2-pyrrolidone and *N*-(n-dodecyl)-2-pyrrolidone are used in household and institutional cleaners, specifically hard-surface cleaners. Annual volumes to this market segment approach 150,000 pounds each.

D. Cumulative Effects

There are no cumulative effects expected since *N*-(n-octyl)-2-pyrrolidone and *N*-(n-dodecyl)-2-pyrrolidone rapidly degrade and the very low use rate is not conducive to build-up in the environment.

E. Safety Determination

1. *U.S. population*. As per the details in the dietary residue exposure system analysis, even the most sensitive population, children, 1 to 6 years old, still would be expected to consume slightly more than 1% of the RfD, for the 4 representative crops analyzed.

2. *Infants and children*. No developmental, embryotoxic, or teratogenic effects have been associated with *N*-(n-octyl)-2-pyrrolidone and *N*-(n-dodecyl)-2-pyrrolidone.

F. International Tolerances

The applicant is not aware of any international tolerance or CODEX of maximum residue limits (MRLs) for *N*-(n-octyl)-2-pyrrolidone and *N*-(n-dodecyl)-2-pyrrolidone on any crop or livestock commodities.

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ENVIRONMENTAL PROTECTION AGENCY

[PF–960; FRL–6737–4]

Notice of Filing Pesticide Petitions to Establish Exemptions from the Requirement of Tolerances for Certain Pesticide Chemicals in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by docket control number PF–960, must be