TABLE 1.—REGISTRATIONS WITH REQUESTS FOR AMENDMENTS TO DELETE USES IN CERTAIN PESTICIDE REGISTRATIONS

Registration no.	Product name	Active ingredient	Delete From Label
000070–00223	AllPro Exotherm Termil	Chlorothalonil	Greenhouse tomatoes
000400–00490	Lindane 40%	Lindane	Cabbage, cauliflower, broccoli, brussels sprouts and radishes
001812–00328	Trilin 10G	Trifluralin	Eggplant, onion uses
005481–00153	ALCO Equine Spray	Dipropyl isocinchomeronate; piperonyl butoxide; pyrethrins; N-Octyl bicycloheptene dicarboximide	Animals intended for human consumption
042056–00014	TCI Captan-Lindane Seed Treatment	Lindane; Captan	Spinach, cabbage, cauliflower, broccoli, brussel sprouts, and radishes
062719–00080	Lontrel T Technical	Clopyralid	Residential turf

Users of these products who desire continued use on crops or sites being deleted should contact the applicable registrant before dates indicated in DATES section of this notice to discuss withdrawal of the application for amendment. This 180–day period, or 30–day where indicated, will also permit interested members of the public to intercede with registrants prior to the Agency's approval of the deletion.

Table 2 includes the names and addresses of record for all registrants of the products in Table 1, in sequence by EPA company number.

TABLE 2.—REGISTRANTS REQUESTING AMENDMENTS TO DELETE USES IN CERTAIN PESTICIDE REGISTRATIONS

EPA Company no.	Company Name and Address
000070	Value Gardens Supply, LLC, Box 585, St. Joseph, MO 64502
000400	Crompton Mfg. Co., Inc., 74 Amity Rd, Bethany, CT 06524
001812	Griffin L.L.C., Box 1847, Valdosta, GA 31603
005481	AMVAC Chemical Corp., Attn: Jon C. Wood, 4695 Macarthur Ct., Suite 1250, Newport Beach, CA 92660
042056	Trace Chemicals LLC, 2320 Lakecrest Drive, Pekin, IL 61554
062719	Dow Agrosciences LLC, 9330 Zionsville Rd 308/2E225, Indianapolis, IN 46268

III. What is the Agency Authority for Taking This Action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be amended to delete one or more uses. The Act further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, the Administrator may approve such a request.

IV. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for use deletion must submit such withdrawal in writing to James A. Hollins, at the address under **FOR FURTHER INFORMATION CONTACT**, postmarked on or before February 24, 2003, or on or before September 27, 2002 for products with registrations number 000400–00490, 0042056–00014, and 005418–00152.

V. Provisions for Disposition of Existing Stocks

The Agency has authorized the registrants to sell or distribute product under the previously approved labeling for a period of 18 months after approval of the revision, unless other restrictions have been imposed, as in special review actions. There is a 12–month existing stocks provision for Dow AgroSciences, EPA Registration Number 062719–00080, after approval of revised label.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: August 16, 2002.

Arnold E. Layne,

Acting Director, Information Resources and Services Division.

[FR Doc. 02–21677 Filed 8–27–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0185 FRL–7194–6]

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–2002–0185, must be received on or before September 27, 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–2002–0185 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–2002–0185. 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–2002–0185 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 ID number OPP–2002–0185. 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: August 16, 2002.

Debra Edwards,

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 Lyondell Chemical Company and represents the view of Lyondell Chemical Company. EPA is publishing the petition summary verbatim without editing it in any way. 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.

Lyondell Chemical Company

PP 2E6484

EPA has received a pesticide petition (2E6484) from Lyondell Chemical Company, 1221 McKinney Street, Suite 1600, Houston, TX 77253–2583 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for 2-methyl-1, 3-propanediol in or on all raw agricultural commodities. 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* The nature of the residues of 2-methyl-1,3-propanediol in plants has not been studied. However, biodegradability studies suggest that the primary residue is the parent, as 2-methyl-1, 3-propanediol is slowly degraded by microorganisms. However, once metabolism by microorganisms is initiated, complete degradation to carbon dioxide and water results.

2. *Analytical method.* An exemption from tolerance is requested for 2-methyl-1,3-propanediol. Therefore, an analytical method for measurement of residues is unnecessary.

3. *Magnitude of residues.* Calculated maximum residues, based on the maximum concentration of pesticides in food crops, are approximately 19 milligrams/kilogram (mg/kg) commodity.

B. Toxicological Profile

1. *Acute toxicity*—i. *Acute oral toxicity in rats.* Five healthy male and five healthy female albino rats were dosed orally with 2-methyl-1, 3-propanediol at 5.0 g/kg of body weight. The rats were observed at 1–, 2– and 4– hours post dose and twice daily for 14 days for mortality and toxicity. Body weights were recorded pretest, weekly and at termination. All animals were examined for gross pathology. All animals survived the 5.0 g/kg oral dose in generally good health. Physical signs of diarrhea, chromorhinorrhea and soiling of the anogenital area were noted during the observation period. Body weight increases were normal. Necropsy results were normal in 8–10 animals. Soiling of the anogenital area and pink fluid in the urinary bladder were noted in two animals. The LD_{50} is greater than 5.0 g/kg of body weight.

ii. *Acute dermal toxicity in rabbits.* Five healthy male and five healthy nulliparous and non-pregnant female New Zealand albino rabbits were dosed dermally with 2-methyl-1, 3-propanediol at 2.0 g/kg of body weight. The test article was kept in contact with the intact skin for 24 hours. The rabbits were observed 1, 2 and 4 hours post dose and twice daily for 14 days for mortality and toxicity. Body weights were recorded pretest, weekly and at termination. Skin reactions were scored on days 1, 7 and 14. All rabbits were examined for gross pathology. Abnormal tissues were preserved in 10% buffered formalin for possible future microscopic examination. Nine of ten animals survived the 2.0 g/kg dermal application. One female died on day 12 with no abnormal predeath physical signs. Necropsy of the dead animal revealed abnormalities of the lungs, pleural cavity, liver and gastrointestinal tract, as well as soiling of the anogenital area and red staining around the mouth. Physical signs noted in survivors included diarrhea, yellow nasal discharge, few feces, bloated abdomen and soiling of the anogenital area. Body weight changes were normal in 7 of 9 survivors. Two animals lost weight during the study. Dermal reactions, absent to slight on day 1, were absent on days 7 and 14. Necropsy results of survivors were normal in 4 of 9 animals. Abnormalities of the kidneys and gastrointestinal tract, as well as soiling of the anogenital area were noted in the remaining animals. In addition, one animal exhibited a tissue mass and hemorrhagic areas on the dorsal abdominal cavity. The LD_{50} is greater than 2.0 g/kg of body weight. The one death did not appear to be related to the effect of the test article, as the animal appeared normal for 11 days.

iii. *Primary dermal irritation in rabbits.* Six healthy New Zealand Albino rabbits were dosed dermally with 2-methyl-1, 3-propanediol. 0.5 milliliter (mL) of the test article was applied to two intact and two abraded sites/rabbit for a total dose of 2.0 mL/rabbit. The test article was kept in contact with the skin for 4 hours at which time the wrappings were removed and dermal reactions were scored at 4, 24, 48 and 72 hours after test article application. The skin was also evaluated for ulceration and necrosis or any evidence of tissue destruction at these time periods. There was no erythema or edema noted during the observation period.

iv. *Eye irritation in rabbits.* Nine healthy New Zealand albino rabbits, free from evidence of ocular irritation or corneal damage, as determined by pretest fluorescein dye procedures, were dosed with 2-methyl-1, 3-propanediol. 0.1 mL of the test article was placed into the conjunctival sac of one eye of each rabbit. Six eyes remained unwashed. Three eyes were washed 20–30 seconds after dosing for 1 minute with lukewarm water. The eyes were examined and scored by the Draize technique on days 1, 2 and 3. The primary eye irritation score for each rabbit, each day, was calculated. The daily average and range were also calculated. UNWASHED: All six eyes appeared normal during the study. WASHED: There was no corneal opacity or iritis. Slight conjunctival irritation, noted in 1 of 3 eyes, cleared by day 2. Two eyes appeared normal during the study.

v. *Acute 4–hour inhalation toxicity in rats.* The acute inhalation toxicity of 2-methyl-1, 3-propanediol was studied by nose-only exposure of one group of five male and five female rats to a test atmosphere containing the limit concentration of 5.1 and 0.2 g/2-methyl-1, 3-propanediol per m^3 for a 4–hour period. The mass median aerodynamic diameter (MMAD) of the particles in the

aerosol was 2.4 frequent modulation (Fm) with a mean geometric standard deviation of 1.4. After exposure, the rats were kept for a 14–day observation period. Except for a slightly decreased breathing rate in the fourth hour of exposure in one female animal, no exposure-related abnormalities were seen during or shortly after exposure or during the 14–day observation period and no mortality occurred. For rats of this strain and age, mean body weight gain was considered to be within the normal range. Findings at necropsy were limited to the lungs. Thickened hyalin spots or small areas were seen on all lobes of the lungs in all female and in three male animals. In a fourth male animal small white areas were seen on all lobes of the lungs. It was concluded that the 4–hour LC_{50} value of 2-methyl-1, 3-propanediol is higher than 5.1 g/m^3 for both sexes.

vi. *Dermal sensitization guinea pig maximization test.* 2-Methyl-1, 3-propanediol was evaluated for delayed contact hypersensitivity (skin sensitization) in guinea pigs that received intradermal and epidermal exposures. The study was carried out in accordance with the Organization for Economic Cooperation and Development (OECD) Guideline No. 406, ''Skin Sensitization'', EEC Directive 84/449/EEC, Part B.6, ''Skin Sensitization'' and in accordance with the method described by Magnusson and Kligman, ''Allergic Contact Dermatitis in the guinea pig - Identification of Contact Allergens''. In order to identify the slightly irritating and the non-irritating test substance concentrations, a preliminary study was carried out. In the main study, the experimental animals were intradermally injected with a 10% concentration and epidermally exposed to the undiluted test substance, while the control animals were similarly treated, but with the vehicle only and with a dry patch. Immediately after the epidermal exposure, the skin irritation was scored. Two weeks after the epidermal application all animals were challenged with test substance concentrations of 100%, 50% and 25%, and the vehicle distilled water. The challenge reactions were assessed 24–48 hours after bandage removal. The epidermal exposure of 2-methyl-1, 3-propanediol in the induction phase resulted in no skin irritation. The epidermal exposure of 2-methyl-1, 3-propanediol in the challenge phase resulted in three positive sensitization reactions in response to the 50% test substance concentration. Under the conditions used in this study, 2-methyl-1, 3-propanediol resulted in a sensitization rate of 15%. Applying the rating of allergenicity described by Kligman A.M. (1966) on the results obtained in this test, 2-methyl-1, 3-propanediol is considered to have mild sensitizing properties.

2. *Genotoxicty*—i. *Mutagenic Activity of 2-methyl-1,3-propanediol in an in vitro mammalian cell gene mutation test with V79 (Chinese hamster cells).* 2-Methyl-1,3-propanediol was tested in an *in vitro* mammalian cell gene mutation test with V79 chinese hamster cells in the presence and absence of a metabolic activation system (S9-mix). 2-Methyl-1,3-propanediol was tested up to and including a concentration of 5,000 milligram/milliliter (mg/mL) in the absence and presence of S9-mix. 2-Methyl-1, 3-propanediol did not induce a significant, dose-related increase in the mutant frequency at the hypoxanthine phophoribosyl transferase (HPRT-locus), either with or without metabolic activation, in two independently repeated experiments. Under the same conditions the positive control chemicals ethylmethanesulphonate (6 mm) and dimethylnitrosamine (8mm) produced 14–23–fold and 8–10 fold increases respectively in the mutant frequency, demonstrating the sensitivity of the assay and the metabolizing activity of the S9-mix. It was concluded that 2-methyl-1,3-propanediol is not mutagenic in the V79/HPRT gene mutation test system under the experimental conditions described in this report.

ii. *Chromosomal aberrations in cultured peripheral human lymphocytes.* 2-Methyl-1,3-propanediol was examined for the induction of chromosome aberrations in cultured peripheral human lymphocytes in the presence and absence of a metabolic activation system (Aroclor-1,254 induced rat liver S9-mix). 2-Methyl-1,3-propanediol was tested up to and including 500 mg/mL in the absence and presence of S9-mix for a 24 hour and a 48 hour fixation period in the first experiment, and for a 24 hour fixation period in the second experiment. None of the tested concentrations induced a statistically and biologically significant increase in the number of cells with chromosome aberrations, either in the absence or in the presence of S9-mix. Positive control chemicals, mitomycin concentration (C) and cyclophosphamide, both produced a statistically significant increase in the incidence of cells with chromosome aberrations, indicating that the test conditions were optimal and that the metabolic activation system (S9-mix) functioned properly. It is concluded that 2-methyl-1, 3-propanediol is not clastogenic in human lymphocytes under the experimental conditions described in this report.

iii. *Ames Salmonella/Microsome Test.* 2-Methyl-1, 3-propanediol was tested in the Ames *Salmonella*/microsome plate test up to and including a concentration of 5,000 mg/plate in the absence and presence of S9-mix. The test substance did not induce a dose-related increase in the number of reverent (His+) colonies in each of the four tester strains (TA1535; TA1537; TA98 and TA100). These results were confirmed in an independently repeated experiment. The test substance was not considered mutagenic in this test system.

3. *Reproductive and developmental toxicity*—i. *Embryotoxicity and Teratogenicity Study.* Timed pregnant female wistar rats were administered 2-methyl-1, 3-propanediol at dosage levels of 300, 600 or 1,000 mg/kg body weight by oral gavage daily on gestation days 0 to 20. Control group females received daily oral administration of water (Milli-U). Female body weights were determined daily and food consumption of females was determined at periodic intervals during pregnancy. On day 21 of gestation, all females were euthanized and subjected to examination post-mortem and external, thoracic and abdominal macroscopic findings were recorded. The ovaries, and uterine horns were dissected and examined for the number of *corpora lutea*, the weight of the gravid uterus, the number and distribution of live fetuses and embryo-fetal deaths, the weight and sex of each live fetus and externally visible foetal macroscopic abnormalities. Alternate live fetuses of each litter were preserved in 96% ethanol or Bouin's fluid, and subjected to skeletal or visceral examinations respectively.

Oral dosing of pregnant female wistar rats with 2-methyl-1, 3-propanediol, at dose levels of 300, 600 or 1,000 mg/kg body weight/day during days 0 to 20 of gestation inclusive, revealed no maternal toxicity.

Treatment at 600 and 1,000 mg/kg body weight/day was associated with a slight increase in embryonic resorptions and a corresponding slight decrease in live litter size, compared with the concurrent controls. However, as all values remained within the laboratory background control ranges, the findings were considered to be of doubtful toxicological significance.

There was no indication of an adverse effect of 2-methyl-1, 3-propanediol on morphological development or skeletal ossification *in utero*.

In this embryotoxicity and teratogenicity study, the no observed effect Level (NOEL) was 300 mg/kg body weight/day.

At the request of Lyondell Chemical Company, an independent review of the embryotoxicity and teratogenicity study was conducted by a reproductive and developmental toxicity expert, L. Irvine (TAS-Environ). The purpose of the review was to clarify the slight changes on embryonic resorptions and litter size that were observed in the original study. The reviewer examined the detailed animal data from the first study and control animal developmental/reproductive performance incidence data from another laboratory with recent experience with the same rat strain and supplier and historical data obtained from the animal supplier. The latter information was included in the review due to the laboratory's limited control data on this rat strain that was available for interpretation of the 2-methyl-1, 3-propanediol study.

The reviewer found the following: (1) In comparison with the available data, it was obvious that the incidence of embryonic deaths in the control group of the 2-methyl-1, 3-propanediol study was unusually low and that the values in the treated groups were more typical for the strain; (2) statistically significant inter-group differences in embryonic resorptions would not have been expected in comparison with a more representative control group; and (3) since there were no other indications of potential embryotoxicity and since there was clearly no dose-related difference in mean live litter size, one could strengthen the study conclusion to state the findings are highly unlikely to be of toxicological significance.

The findings of the TAS-Environ review support and strengthen the original conclusions that discount the toxicological significance of changes in embryonic resorptions and litter size observed for 2-methyl-1, 3-propanediol in the embryotoxicity and teratogenicity study.

ii. *Prenatal developmental toxicity in rats.* The potential maternal toxicity and prenatal developmental toxicity of the test article, 2-methyl-1, 3-propanediol were evaluated. The test article in the vehicle, deionized water, was administered to three groups of 25 bred Crl:CD (SD)IGS BR rats once daily from gestation days 0 through 19. Dosage levels were 100, 300 and 1,000 mg/kg/day administered at a dose volume of 5 mL/kg. A concurrent control group composed of 25 bred females received the vehicle, deionized water, on a comparable regimen at 5 mL/kg. The route of administration was oral by gastric intubation. Clinical observations, body weights and food consumption were recorded. On gestation day 20, a laparohysterectomy was performed on all animals. The uteri and ovaries were examined and the numbers of fetuses, early and late resorptions, total implantations and *corpora lutea* were recorded. Mean gravid uterine weights and net body weight changes were calculated for each group. The fetuses were weighed, sexed and examined for external, soft tissue and skeletal malformations and variations.

All maternal animals survived to the scheduled necropsy on gestation day 20. No treatment-related clinical findings were observed at any dose level. Body weights, body weight gains, gravid uterine weights, net body weights, net body weight gains and food consumption were unaffected by treatment at any dose level. No test article-related internal findings were observed in the dams at any dose level.

Intrauterine growth and survival were unaffected by test article administration at any dose level. The fetal malformations and developmental variations observed in the treated groups were considered to be spontaneous in origin.

Based on the results of this study, the no observed adverse effect level (NOAEL) for maternal toxicity and prenatal developmental toxicity is 1,000 mg/kg/day, the highest dose level tested.

iii. *Two-generation reproductive toxicity study in rats.* This study was conducted to evaluate the potential adverse effects of 2-methyl-1, 3-propanediol administration on the reproductive capabilities of the F_0 and F_1 generations and on F_1 and F_2 neonatal survival, growth, and development. The test article was administered orally by gavage once daily for at least 70 consecutive days prior to mating to three groups of F_0 and F_1 parental Crl:CD (SD)IGS BR rats (30/sex/group). A control group of identical design received deionized water on a comparable regimen. Test article administration continued throughout mating, gestation and lactation, until euthanasia for F_0 and F_1 parental animals. All parental animals were observed twice daily for appearance and behavior. Clinical observations, body weights, and food consumption were recorded at appropriate intervals prior to mating and during gestation and lactation. All F_0 and F_1 females were allowed to deliver and rear their pups until weaning on lactation day 21. On lactation day 21, 35 pups/sex/group from the pairing of the F_0 animals, including five potential replacement animals/sex/group were selected for use in the F_1 generation. These animals were dosed from postnatal day (PND) 22–27, inclusively. On PND 28, 30 offspring/sex/group were selected to constitute the F_1 generation. The remaining 5 offspring/sex/group were submitted for necropsy. Developmental landmarks anogenital distance, balanopreputial separation and vaginal patency were evaluated for the selected F_1 rats. Unselected F_0 and F_1 pups were necropsied on postnatal day (PND) 21–28; selected organs were weighed on PND 21. All surviving F_0 and F_1 parental animals received a complete detailed gross necropsy following the completion of weaning of the F_0 and F_1 pups, respectively; selected organs were weighed. Spermatogenic endpoints (sperm motility, morphology and numbers) were recorded for all F_0 and F_1 males, and ovarian primordial follicle and *corpora lutea* counts and the presence or absence of growing and antral follicles were recorded for 10 F_0 and 10 F_1 females in each of the control and high-dose groups. Designated tissues from 10 F_0 and F_1 parental animals/sex/group in the control and 1,000 mg/kg/day groups and from all parental animals that were found dead or euthanized in extremis were examined microscopically. In addition, any tissues that appeared abnormal were also examined microscopically.

No test article-related mortalities or clinical findings were observed in the F_0 or F_1 generation. One F_0 male in the 300 mg/kg/day group was euthanized in extremis during week 2 due to shallow, slow respiration and excreta-related findings on the day prior to and on the day of euthanasia. At necropsy, this animal had a dilated left renal pelvis (hydronephrosis) and white content and white areas on the right renal pelvis. The pathology for this animal was determined microscopically to be pyelonephritis. All other F_0 animals survived to the scheduled necropsy. In the F1 generation, one control group female was found dead during study week 27 (prior to pairing) due to accidental mechanical trauma to the neck. All F_1 animals that were paired survived to the scheduled necropsy.

Reproductive parameters were not adversely affected by test article administration at dose levels of 100, 300 and 1,000 mg/kg/day during the F_0 or F_10 generations. No adverse test article-related effects on weekly, gestation or lactation body weight, body weight gain, food consumption or food efficiency were observed in the F_0 or F_1 generations.

No test article-related macroscopic or microscopic internal findings were observed in the F_0 or F_1 generation

males or females. Absolute and relative (to final body weight) organ weights were unaffected by test article administration for males and females in the F_0 or F_1 generations.

Mean F_0 or F_1 pup body weights, sex ratios, live litter sizes, numbers of dead pups on lactation day 0 and viability indices were unaffected by test article administration. No test article-related effects on physical development or behavioral responses were observed for the F1 pups.

No test article-related internal findings were noted in the F_0 or F_1 pups that died or were euthanized, or at the scheduled necropsies. Necropsy findings for the selected weanling pups did not suggest any effects of test article administration. No test article-related effects on estrous cycle or gestation length, parturtion, ovarian primordial, follicle and corpora lutea counts, the presence of growing and antral follicles, implantation site counts or spermatogenic endpoints sperm motility, morphology and numbers were observed in either the F_0 or F_1 generation.

In conclusion, no parental, neonatal or reproductive toxicity was observed as a result of test article administration at dose levels of 100, 300 and 1,000 mg/kg/day. Based on the results of this study, the no-observed-adverse-effect level (NOAEL) for parental, neonatal and reproductive toxicity is 1,000 mg/kg/day.

4. *Subchronic toxicity*—i. *Sub-acute 14–day oral toxicity in the rat.* In this subacute 14–day toxicity study, 2-methyl-1, 3-propanediol was administered daily by gavage to SPF-bred wistar rats at 300, 600 or 1,000 mg/kg/day, in order to provide a basis for selection of dose levels for a 90–day study. All animals were subjected to daily clinical observation. Body weight was measured on day 1, after 1 week and on the day before necropsy and food consumption weekly. During week 2 of treatment, both eyes of all animals were examined. On the day of termination blood was collected from each animal for clinical laboratory investigations. Subsequently, macroscopic observations and organ weights were recorded. A histopathological examination was performed on adrenals, heart, kidneys, liver, spleen, stomach and testes. There were no treatment-related changes for any of the treatment groups for the parameters evaluated. From the results presented in this report, a definitive no observed effect level (NOEL) of 1,000 mg/kg/day was established.

ii. *90–day oral toxicity in the rat.* In this sub-chronic 90–day oral toxicity study, 2-methyl-1, 3-propanediol was administered daily by gavage to SPF-bred Wistar rats. The study consisted of 4 groups, each comprising 10 males and 10 females, and dosed at 0, 300, 600 or 1,000 mg/kg/day. Dose levels were selected based on the results of a 14–day range finding study. (RCC NOTOX 09171).

All animals were subjected to daily clinical observation. Body weight and food consumption were measured weekly and, for body weights, also on the day of necropsy. Ophthalmoscopic examinations were performed prior to commencement of treatment on all animals and at week 13 on all animals of the control and high dose groups. During the last week of treatment (week 13) blood was collected from each animal for clinical laboratory investigations. At the end of week, all animals were necropsied and macroscopic observations and organ weights recorded. Samples of all tissues were taken and fixed. A selection of organs from animals of the control and high dose groups were histologically processed and subsequently subjected to pathological examination.

There were no treatment-related changes for any of the treated groups for the parameters evaluated. From the results presented in this report, a definitive no observed effect level (NOEL) of 1,000 mg/kg/day was established.

5. *Chronic toxicity.* Neither oncogenicity nor 2–year feeding studies in animals have been completed using 2-methyl-1, 3-propanediol as the test material.

6. *Endocrine disruption.* Nothing in the available literature suggests that 2-methyl-1, 3-propanediol is an endocrine disruptor or that it possesses intrinsic hormonal activity.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food.* The inert, 2-methyl-1, 3-propanediol, will be added to water-soluble pesticide formulations as a solvent and/or surfactant. These pesticide formulations will be applied to raw agricultural commodities as insecticides, herbicides or fungicides. The maximum amount of 2-methyl-1,3-propanediol in any particular formulation is expected to represent no more than 4% of the formulation or a maximum of 8 pounds of 2-methyl-1, 3-propanediol per acre of crop.

The amount of 2-methyl-1,3-propanediol expected to be present in crops grown for human consumption is estimated based on the maximum potential residues of 2-methyl-1,3-propanediol on ready-to-eat raw agricultural commodities (i.e., scraped, peeled, washed, etc.) taken from the USDA Pesticide Data Program (1999).

Potential residues of 2-methyl-1,3-propanediol were estimated from USDA pesticide residue studies from ready-to-eat fruits and vegetables. It has been projected that 2-methyl-1,3-propanediol will represent no more than 4% of any given pesticide formulation. However, as there are currently no data to describe the affinity that 2-methyl-1, 3-propanediol may have for particular crops or for specific areas of a crop (i.e., skin, root, leaf), Lyondell Chemical Company assumed that 100% of 2-methyl-1, 3-propanediol applied remains on the treated crop, a very conservative assumption. The highest pesticide residue, 19.0 mg/kg food, was measured for fresh strawberries. Assuming that 3.0 kg food (solids and liquids) are consumed per day and that the maximum residue calculated for fruits and vegetables is present in the entire diet 19 mg/kg food, the estimated daily intake (EDI) for an adult weighing 71.8 kg is 0.8 mg 2-methyl-1, 3-propanediol/kg/day and the EDI for a child weighing 22.0 kg is estimated to be 2.58 mg 2-methyl-1, 3-propanediol/kg/day.

a. *Acute exposure.* Acute oral toxicity studies on 2-methyl-1,3-propanediol conclude that adverse effects in rats and mice were seen throughout the 14 day observation period. Though a LOAEL was not established in either study, Lyondell Chemical Company determined a LOAEL of 5,000 mg/kg is reasonable based on the observations of initial adverse effects. Observable effects included diarrhea, chromorhinorrhea and soiling of the anogenital area. These effects were observable during the 14 days after dosing, and though no animals died, they can be considered observable adverse effects. The calculated acute reference dose (RfD) is 16.0 mg/kg/day based on the estimated acute toxicity LOAEL (5,000 mg/kg/day) and the appropriate uncertainty factors accounting for potential intraspecies variation, for potential interspecies variation, and the use of an estimated LOAEL in place of a NOAEL (10 x 10 x 3 or 300–fold uncertainty factor).

b. *Chronic Exposure.* The calculated chronic RfD is based on a two-generation reproductive toxicity study, in which the paternal, neonatal and reproductive NOAEL was determined to be 1,000 mg/kg/day. Using the appropriate uncertainty factors accounting for the potential intraspecies variation, for potential interspecies variation, and a worst case modifying factor (10 x 10 or 100–fold uncertainty

factor), the chronic RfD is estimated to be 10.0 mg/kg/day.

ii. *Drinking water.* The theoretical residues calculated for dietary intake included intake from drinking water (one-half of the 3 kg food consumed per day is assumed to be liquids.) Since 2-methyl-1, 3-propanediol is a surfactant, and is water soluble, it is expected that some exposure in drinking water will occur. However, it is unlikely that drinking water exposures exceeding those calculated above, assuming direct application of pesticides containing this inert would occur due to runoff or leaching into groundwater. Biodegradability studies indicate that 2-methyl-1, 3-propanediol is inherently biodegradable (modified Sturm test; 54% of the material degraded in the observed time.)

2. *Non-dietary exposure.* 2-Methyl-1, 3-propanediol is currently used as a neutralizer, emollient, emulsifier, and humectant in numerous personal care products. The chemical is also used in the synthesis of polyester polyols for solvent and waterborne urethane and high solid and powder polyester coatings. The chemical also holds several FDA approvals and clearances for use in food contact applications, including its use in adhesives, resinous and polymeric coatings, paper and paperboard in contact with aqueous, fatty, and dry foods, slimicides, and polyurethanes in contact with bulk dry food.

D. Cumulative Effects

There is insufficient information to determine whether other compounds have a common mechanism of toxicity to 2-methyl-1, 3-propanediol.

E. Safety Determination

1. *U.S. population.* Using the above estimated RfDs, the adult estimated daily intake (EDI) represents 5 percent of the acute RfD and 8 percent of the chronic RfD. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. It should be noted that the exposures estimates are conservative and exaggerated.

2. *Infants and children.* The EDI for a child represents 16 percent of the acute RfD and 26 percent of the chronic RfD. Based on these data, it may be concluded that there is a reasonable certainty that no harm will result from aggregate exposure to 2-methyl-1, 3-propanediol residues to the U.S. population, including both adults and children.

F. International Tolerances

There are no international tolerances listed for 2-methyl-1, 3-propanediol.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL–7269–3]

Underground Injection Control (UIC) Program; Hydraulic Fracturing of Coalbed Methane (CBM) Wells Report—Notice

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability of draft report and request for comment.

SUMMARY: The Environmental Protection Agency (EPA) has completed a draft report titled, ''Evaluation of Impacts to Underground Sources of Drinking Water by Hydraulic Fracturing of Coalbed Methane Reservoirs'' EPA 816–D–02–006. The draft report contains the preliminary results of Phase I of an investigation undertaken by EPA to evaluate the impacts to underground sources of drinking water (USDW) by hydraulic fracturing of coalbed methane wells (herein known as hydraulic fracturing). Based on the information collected, EPA has preliminarily found that the potential threats to public health posed by hydraulic fracturing of CBM wells appear to be small and do not appear to justify additional study. The purpose of this notice is to inform the public of the availability of the draft report for review and to seek public comment on the draft report.

DATES: EPA must receive public comment, in writing, on the draft report by October 28, 2002.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in section I of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: L. Cronkhite, Ground Water Protection Division, Environmental Protection Agency, Mail Code 4606M, Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, PH: (202) 564–3878. E-mail: *cronkhite.leslie@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. How Can I Get Copies of the Draft Report, ''Evaluation of Impacts to Underground Sources of Drinking Water by Hydraulic Fracturing of Coalbed Methane Reservoirs'' and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under Docket ID No. W–01–09–II. The official public docket consists of the *Draft Report, Evaluation of Impacts to Underground Sources of Drinking Water by Hydraulic Fracturing of Coalbed Methane Reservoirs,* documents referenced in this action, any public comments received, and other information related to this action. The official public docket is the collection of materials that is available for public viewing beginning August 27, 2002 at EPA's Water Docket at 1301 Constitution Ave., NW., Room B135, Washington, DC 20004. The OW Docket is closed from August 12 through August 26, 2002, for relocation. This Docket Facility is open from 9 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (202) 566–2426.

2. *Electronic Access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access draft report, ''Evaluation of Impacts to Underground Sources of Drinking Water by Hydraulic Fracturing of Coalbed Methane Reservoirs,'' access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket identification number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket