(OCHP) activities and a presentation on assessing cancer risks from early life exposure. Other potential agenda items include a panel discussion of the NAS review of EPA's Perchlorate Risk Assessment, and a presentation on PBDE.

Dated: February 2, 2005.

Elizabeth H. Blackburn,

Acting Designated Federal Official.

U.S. Environmental Protection Agency

Children's Health Protection Advisory Committee, Hotel Washington, 515 15th Street, NW., Washington, DC 20004–1099, February 22–24, 2005

Draft Agenda

Tuesday, February 22, 2005

Work Group Meetings

Wednesday, February 23, 2005

Plenary Session

9:00 *Welcome, Introductions, Review Meeting Agenda*
9:15 *Highlights of Recent OCHP Activities*
9:45 *Presentation: Cancer Guidelines Update*
10:15 Break
10:30 *Science and Regulatory Workgroup Reports*
12:00 Lunch (on your own)
1:30 *Panel Discussion: NAS Review of EPA's Perchlorate Risk Assessment*
3:00 Break
3:30 *Presentation and Discussion: OCHP Strategic Plan*
5:15 *Public Comment*

Thursday, February 24, 2005

8:45 *Discussion of Day One*
9:00 *Presentation: PBDE Update*
10:15 Break
10:45 *Presentation: Update on EPA's Response to CHPAC Mercury Comment Letters*
11:45 *Wrap Up/Next Steps*

[FR Doc. 05–2611 Filed 2–9–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0010; FRL–7695–9]

Alkyl Ether Amine Dicarboxyethyl Sodium Salts; Notice of Filing a Pesticide Petition to Establish a Tolerance Exemption 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 identification (ID) number OPP–2005–0010, must be received on or before March 14, 2005.

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

FOR FURTHER INFORMATION CONTACT: Keri Grinstead, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8373; e-mail address:*grinstead.keri@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any 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 Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2005–0010. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although, a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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 the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID 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. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or on paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and

without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also, include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2005–0010. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID number OPP–2005–0010. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID number OPP–2005–0010.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID number OPP–2005–0010. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is 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 docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed 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 FFDCA 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: January 25, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

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

Tomah[3] Products, Inc.

PP 4E6861

Summary of Petitions

EPA has received a pesticide petition 4E6861 from Tomah[3] Products, Inc., 337 Vincent Street (P.O. Box 388), Milton, Wisconsin 53563–0388 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 the use of any member of the class of amphoteric surfactant inert ingredients described as [beta-alanine, *N*-(2-carboxyethyl)- *N*-[3-(polyoxaalkylalkoxy)propyl]-, (mono- or disodium salt) and polyalkoxy, a-[3-[bis(2-carboxyethyl)amino]propyl]-w-alkoxy, (mono- or disodium salt), containing 0 to 20 repeating alkoxy/polylalkoxy units (methoxy-, ethoxy-, propoxy-, butoxy-) and 6 to 21 carbons in an n-alkyloxy-, isoalkyloxy- or branched alkyloxy- chain; also known as alkyl ether amine dicarboxyethyl sodium salts, in or on all raw agricultural commodities and food. 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.* Any residues are expected to be parent amphoteric amines as described above.

2. *Analytical method.* Since this petition is for an exemption from the requirement of a tolerance, an analytical method is not required.

3. *Magnitude of residues.* This application is designed to follow EPA's new methodology for the evaluation of low toxicity substances used in pesticide products. To develop exposure estimates, residue data for pesticide active ingredients were used as described below as surrogate data for the class of inert ingredients. Several complementary approaches were used.

Tier 1 Screening Level scenarios (i.e., bounding extreme worst-case) included the following exposure assumptions. Actual crop-specific residue data for active ingredients, including secondary residues were used as surrogates for the surfactants without adjustment for the percentage of inert in the formulation. Data were used for all herbicides used at >5 million pounds/year (lbs/yr) and all fungicides and insecticides used at >1 million lbs/yr, including all active ingredients used in significant amount on the top 25 crops consumed by children; Both acute and chronic exposure levels were determined; The assessment assumed that 100% of all crops are treated with pesticides containing the surfactants.

More sophisticated Tier 2 worst-case scenarios included the following exposure assumptions. For chronic exposure, actual crop-specific residue data are used as surrogates for the surfactants, with adjustment for percentage of the inert in the formulation using an upper-bound value of 17.1%; frequency of detection of pesticides was used as a method of ranking all pesticides monitored in the U.S. for residues. The top 30 pesticides were found to account for 99.9% of the total dietary intake of pesticide residues and were selected as the surrogates to use in estimating exposure. Exposure levels were determined using actual residue and frequency data for the 30 most frequently detected residues.

For acute exposures, EPA's Cumulative OP Acute Dietary Exposure Distribution estimated for children 1–2 years in Florida (EPA, 2002) was used as a surrogate. No adjustment was made to convert the active ingredient exposure for actual percentage of inert ingredient used in the formulation. The methamidophos-equivalent exposure estimates were used directly to approximate the magnitude of potential acute dietary exposures to the amphoteric surfactants. Exposure estimates were made for the 90th%, 95th% and 99.9th% consumption.

B. Toxicological Profile

1. *Acute toxicity.* Only a small amount of primary data are available on the acute toxicity of substances within the proposed class of amphoteric surfactants. These data have been supplemented in the assessment described below by using publicly available data on the toxicology of alkyl amines and related derivatives.

i. *Acute dermal toxicity and eye irritation.* Virtually all of the amines when administered directly or in concentrated solution are primary skin and eye irritants. Animals exposed to concentrated vapors exhibit signs and symptoms of mucous membrane and respiratory tract irritation. Direct skin contact with liquid amines can produce severe burns and necrosis. Little toxicity information is available on amines containing eight or more carbons. But, it is clear that these amines, either as the neat liquid, or in concentrated solution, would be strong local irritants for eyes, skin, and mucous membranes. The lowered vapor pressure for the higher alkyl amines would tend to reduce the hazard from vapor exposure.

ii. *Acute oral toxicity.* Estimated LD_{50} for amphoteric compounds 300 to 500 milligrams/Kilogram (mg/kg). The LD_{50s} for the shorter chain primary amines (C2–C8) are in the 300 to 500 mg/kg range. Secondary amines are slightly more toxic than the corresponding primary amines. As the chains increase in length beyond C12 to C16 there is an observable reduction in toxicity. For example, the acute oral LD_{50} for octadecylamine (C18H39N) in mice and rats is approximately 2–3 gram/kilogram (g/kg) compared to the 300 to 500 mg/kg range for the shorter chain amines. The addition of an alcohol group to the molecule reduces the toxicity significantly. The alkanolamines and the alkylalkanolamines are typically 3–5 times less toxic than their amine congeners. For this reason it is expected that the addition of propoxylate or ethoxylate groups will not confer additional toxicity beyond that of the amine itself, and is likely to tower toxicity substantially.

iii. *Alkyl amines vs alkanolamines.* The acute toxicity of the alkylamines are

reduced from 4 to 20–fold by the introduction of hydroxyl groups into the molecule. The toxicity of the alkyl amines is reduced approximately 5–fold as the molecular weight increases from C2 - C16 and higher.

iv. *Effect of carboxylic acid salts.* This trend of decreasing acute toxicity with the addition of polar groups persists when the added groups are acetate or propionate carboxylic acid salts. These are the groups found in the amphoteric surfactants which are the subject of this submission. The acute toxicity of the C10–C12 alkyl amines is reduced from 2 to 15–fold when the alkyl groups on the nitrogen atom are replaced by either propionate or acetate salts.

2. *Genotoxicity*. There is no indication that any alkyl amine is mutagenic. Zeiger et al. (Ref. 1) reported on the *Salmonella Mutagenicity* of 255 chemicals including 25 alkyl amines. Twenty three of the alkyl amines tested negative in the Ames test both with and without activation and only two substituted amines were weakly positive (*N*-hydroxyethylethylenediamine and monoisopropanolamine).

3. *Reproductive and developmental toxicity*. Genamin TA (CAS # 61790–33–8), a mixture consisting primarily of C16–C18 primary amines was given to both male and female rats 14 days prior to mating continually for 54 days thereafter (Ref. 2). The author noted that the NOAEL for parental toxicity and for effects on offspring was 12.5mg/kg. The reported NOAEL for fertility was 50 mg/kg.

4. *Subchronic toxicity. N*-methyl- *N*-octadecyl-1-octadecanamine was administered to rats for 90–days at doses of 1,500; 5,000; and 15,000 ppm in the diet. Doses were reduced after week 4 to 1,500; 4,000 and 10,000 ppm. The presence of histiocytosis in all groups precluded the establishment of a NOEL in this dose range. The LOAEL was 1,500 ppm or 75 mg/kg/day (Ref. 3). Subchronic studies have also been conducted on a few alkanolamines. Ethomeen T/12 (CAS # 61791–44–4) Ethanol,2,2-iminobis-, *N*-tallow alkyl derivatives at doses of 15, 50, 150, and 450 mg/kg were fed to rats in their diet for 90–days. Ethomeen T/12 is a mixture of polyoxyethylene tallow amines. Gross macroscopic effects were seen and body weight gain was reduced only at the 450 mg/kg level. Microscopic findings were seen in the intestine and regional mesenteric nodes levels of 150 mg/kg and greater. The no observed adverse effect level (NOAEL) was 50 mg/kg and the lowest observed adverse effect level (LOAEL) was 150 mg/kg. A similar study was conducted in dogs at doses of 13, 40, and 120 mg/kg. Vomiting occurred at doses of 40 mg and higher. No gross pathologic variations or lesions were observed in any dose group. Histological evaluation revealed an increase in the incidence of foamy macrophages in the small intestine and regional lymph nodes in the 40 mg/kg and 120 mg/kg dose groups. The NOAEL was 13 mg/kg/day and the LOAEL 50 mg/kg/day (Ref. 4).

5. *Chronic toxicity*. Octadecylamine [CH3(CH2)17 NH2] has been administered to rats in a 2–year rat feeding study (Ref. 5). The NOAEL was 500 parts per million (ppm) in the diet and 3,000 ppm was a LOAEL. Rats fed 3,000 ppm showed some weight loss, anorexia, and some histological changes in the gastrointestinal tract, mesenteric nodes, and liver. This NOAEL gives an ADI of 0.25 mg/kg body weight/day (bwt/day) using a 100–fold safety factor. (500 ppm in old rats corresponds to 25 mg/kg bw/day). An earlier 1–year oral study in dogs by Deichmann (Ref. 6), reported a slight weight decrement at the highest of three doses (0.6, 3.0, and 15 mg/kg bwt/day). The NOEL from this study was 3.0 mg/kg bwt/day. A corresponding ADI would be 0.03 mg/kg bwt/day, or about 8–fold lower than the study in rats.

Most of the amine repeat-dose toxicology studies yield NOAELs in the 3 to 50 mg/kg bwt/day range. The lowest repeated dose NOAEL in these reports is 3.0 mg/kg bwt/day (both rabbit developmental study with olelyamine and 1–year chronic dog study with octadecyl amine). The application of these data for amphoteric amines depends on the toxicity of other members of this surfactant family having the same or lesser order of toxicity as the long chain fatty amines.

The amphoterics in this submission differ from the simpler alkyl amines in two ways; first they are alkoxylated, which introduces polar ether linkages, second they additionally have two charged carboxyl groups on the end of the molecule. Both of these charges make the molecule more polar, and can decrease the systemic toxicity of the substance. The increased polarity canmake the substances easier to eliminate in the urine. The increased number of ether linkages can make the substance harder to absorb. For these reasons, we believe that the NOELS of the ether amines establish an upper bound to the toxicity of the amphoterics at approximately 10 mg/kg bw/day; the amphoterics themselves should be considerably less toxic. Given that there are norepeat-dose toxicity data in animals available on the amphoterics, we have endeavored, via a weight-of-evidence approach, to demonstrate that as the alkyl amine core of the molecule is modified by the introduction of polar constituents, the toxicity is decreased. Thus the toxicity of the amphoterics will be below that of the amines. In the discussion below, we show how the introduction of polar groups reduces the toxicity of several related classes of substances and how an average numerical bound might be placed on this effect.

With reference to the report of the American Chemistry Council's report of the Fatty Nitrogen Derivatives Panel Amines Task Group (Ref. 7), if alkyl (C10 - C16) dimethyl amine oxide is compared to the corresponding or similar alkyl amine it is seen that the toxicity drops by approximately 10-fold. The NOEL for alkyl (C10 - C16) dimethyl amine oxide in a chronic rat study is 42.3 mg/kg bw/day. The NOEL in a 90-day rat study was the same. The urine was the primary pathway for elimination and excretion was largely complete in 24 hours (Ref. 8). In contrast the maternal toxicity NOEL for Cis- 9-octadecenylamine was 10 mg/kg bw/day in rats and 3 mg/kg bw/day in rabbits. The NOEL for octadecylamine in a 1-year oral gavage study in rats was 3 mg/kg bw/day. It is seen that the conversion of the amine to the amine oxide tends to reduce the repeat-dose toxicity by approximately 3 to 10-fold. In a similar manner the acute toxicity of the alkylamines are reduced from 4 to 20-fold by the introduction of hydroxyl groups into the molecule, and the toxicity of the alkyl amines is reduced approximately 5-fold as the molecular weight increases from C2 to C16 and higher.

6. *Animal metabolism*. The aliphatic amines are well absorbed from the gut and respiratory tract. They are either excreted intact or in the form of metabolites, depending on the course of metabolism, which depends on their structure. Monamine oxidases are mitichondrial enzymes that catalyze the oxidation of many primary amines to the corresponding aldehyde and ammonia. The aldehydes are further oxidized to the correspondingcarboxylic acid and the ammonia to urea. In addition microsomal enzymes can metabolize amines not readily transformed by monoamine oxidases, through a variety of pathways. These include: deamination, methylation, *N*-dealkylation, *N*-oxidation, *N*-acetylation, cyclization, *N*-hydroxylation, and nitrosation.

7. *Metabolite toxicology*. Secondary amines are prone to react with nitrite, depending on the pH of the media, to form nitrosamines, some of which are potent animal carcinogens. Some

studies have suggested the possibility of *in vivo* formation of carcinogenic nitrosamines within the acidic environment of the stomach following ingestion of secondary amines. The major human intake of nitrates (~ 50 mg/day) comes from vegetables, water supplies, or additives in the meat and fish curing process (Ref. 9). Nitrates are converted to nitrites in the upper part of the gastrointestinal tract by nitroreductase bacteria normally present in the lower bowel.

Amines or amine precursors are present in vegetables, wine, spirits, beer, tea, fish, food flavoring agents, and some drugs. As indicated above, at least 10 mg of amine nitrogen is excreted per day; the intake of amines or their precursors is therefore probably in the 100 mg/day range. Thus there exists the required elements for the *in vivo* formation of carcinogenic nitrosamines from amine ingestion. Despite this theoretical possibility, epidemiologic studies have not provided evidence for a causal association between nitrite exposure and human cancer. Nor has a causal link been shown between *N*-nitroso compounds preformed in the diet or endogenously synthesized and the incidence of human cancer (Ref. 10). It has been demonstrated in animals that nitrosation of diethylamine and dimethyamine *in vivo* is a very slow process. When these substances were fed to rats together with nitrite for over two years no tumors typical of treatment of rats with nitrosodiethylamine were observed (Ref. 11). In any event, the addition to the diet of nanogram levels of amines from the proposed used of amine based surfactants is insignificant compared to normal endogenous levels and to those naturally occurring in food.

8. *Endocrine disruption*. There is no evidence to suggest that the alkyl amines have an effect on any endocrine system. In developmental and two-generation reproduction toxicity tests systemic toxicity was noted but no developmental or reproductive effects were found.

C. Aggregate Exposure

1. *Dietary exposure*. Exposure through both food and drinking water were estimated using data and methods more commonly applied to pesticide active ingredients. The methods for estimating dietary exposure are discussed above under residues. Drinking water exposures were estimated using EPA's combined Pesticide Root Zone Model/ Exposure Assessment Modeling System (PRZM/EXAMS) and the 1 hectare pond scenario.

i. *Food*. Both Tier 1 and Tier 2, acute and chronic dietary assessments were constructed in several different ways and in general MOEs >100 were found. Tier 1 acute assessments did yield MOEs <100, but the Tier 2 analysis gave an MOE = 1,500 for the lowest Tier 1 scenario.

ii. *Drinking water*. Using the average peak value fromPRZM/EXAMS modeling for acute exposure, the average 60-day concentration for chronic exposure and the standard estimates of water consumption, acute and chronic margins of exposure for drinking water all MOEs were greater than 360. In using the model, maximum application rates and number of applications were assumed and the amphoteric surfactants were assumed not to degrade in water or the environment. The modeling provides an extreme worst-case estimate of exposure in that the peak values simulated accumulation (i.e., no degradation) of the surfactants in water during a 30 years period of application.

2. *Non-dietary exposure*. For non-dietary exposure and risk analysis outdoor lawn care with broadcast application via hose-end sprayer was selected as the worst case. Dermal absorption was assumed to be 10%. Applicators were assumed to have dermal and inhalation exposures, while re-entry exposures were dermal and oral, the oral via hand-to-mouth activities by children. MOE's >100 were estimated by Tier 1 analyses, indicating reasonable certainty of no harm for the worst-case bounding scenario evaluated.

D. Cumulative Effects

Other amphoteric amine compounds may be used in pesticide formulations. However, the assessment of this class of compounds assumes 100% of the pesticide products applied to crops will use one member of this class of amphoteric amines. Therefore, the cumulative risk for this class of compound is covered by the assessments in this submission.

E. Safety Determination

1. *U.S. population*. As a general rule in any pesticide assessments, exposures of children are the highest of any subpopulation. This pattern was found to hold true for the amphoteric surfactants and lead to simplifications in the assessment procedure. When exposures to children were found to be acceptable, e.g., acute and chronic Tier 2 estimated dietary exposures to children yielded large MOEs, separate estimates for other subpopulations were not deemed necessary. In the risk assessment we ultimately have adopted the dietary exposures for children for all subpopulations. Exposures for females 13 to 49 were calculated in certain instances and found to be comparable to each other and less than for children. Hence, exposure estimates for the latter were not formally completed. Rather the exposure numbers for females were assumed for the full U.S. population.

2. *Infants and children*. Except when using acute Tier 1 dietary exposure estimates and the most conservative toxicity endpoint, 3 mg/kg-bw/day, all MOEs were found to be comfortably greater than 100. Given the worst-case conservatism built into all the analyses, the results support a conclusion that Tomah[3]'s amphoteric surfactants may be used safely in pesticide formulations without concerns for dietary and non-occupational exposures.

F. References

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2. Bussi R (2000). ''Genamin TA100: Reproduction/Development toxicity Screening Test in rats by oral route.'' APAG, Instituto di Recerche Biomediche, 'Santoine Marxer' S.p.a.

3. Procter and Gamble, Ref. 3) EPA submission, No. 88—9200007039, microfiche No. 0T5537649.

4. Goater T.O., Griffiths D., McElliogott T.F., and AAB Swan, A.A.B, (1970), ''Summary of toxicology data - acute oral toxicity and short-term feeding studies on polyoxythylene tallow amines in rats and dogs,'' *Food and Cosmetics Toxicology* 8:249—252.

5. Deichmann, W.B., Radomski, J.I., MacDonald, W.E., Kascht, R.L., and Erdman, R.l., (1958), American Medical Association *Archives of Industrial Health*, 18:483.

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7. Fatty Nitrogen Derivatives Panel Amines Task Group, 2002, Fatty Nitrogen Derived (FND) Amines Category High Production Volume (HPV) Chemicals Challenge, American Chemistry Council, Washington, D.C.

8. U.S. EPA. 1999. The Use of Structure-activity Relationships (SAR) in the High Production Volume Chemicals Challenge Program. http://www.epa.gov/ch emrtk/sarfinl1.htm.

9. Ellen et al. 1990. Food Additives Contaminants 7(2):207—221.

10. Gangilli., S.D., 1999, ''Nitrate, nitrite and *N*-nitroso compounds''in Ballintine, B., Marrs, T., and Turner, P., *General and Applied Toxicology*, Stockton Press, New York, p 2111, 2143.

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[FR Doc. 05–2620 Filed 2–9–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7871–4]

Carolina Steel Drum Superfund Site; Notice of Proposed Settlement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed settlement.

SUMMARY: The United States Environmental Protection Agency is proposing to enter into a settlement for the partial reimbursement of past response costs with fifty-four (54) de minimis parties pursuant to section 122 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. 9622(h)(1) concerning the Carolina Steel Drum Superfund Site (Site) located in Rock Hill, York County, South Carolina. EPA will consider public comments on the proposed settlement for March 14, 2005. EPA may withdraw from or modify the proposed settlement should such comments disclose facts or considerations which indicate the proposed settlement is inappropriate, improper or inadequate. Copies of the proposed settlement are available from: Ms. Paul V. Batchelor, U.S. EPA, Region 4, (WMD–SEIMB), 61 Forsyth Street, SW., Atlanta, Georgia 30303, (404) 562–8887, *Batchelor.Paula@EPA.Gov.*

Written comments may be submitted to Ms. Batchelor within 30 calendar days of the date of this publication.

Dated: January 26, 2005.

Rosalind H. Brown,

Chief, Superfund Enforcement & Information Management Branch, Waste Management Division.

[FR Doc. 05–2612 Filed 2–9–05; 8:45 am]

BILLING CODE 6560–50–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7871–5]

Carolina Steel Drum Superfund Site; Notice of Proposed Settlement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed settlement.

SUMMARY: The United States Environmental Protection Agency is proposing to enter into a settlement for the partial reimbursement of past response costs with the de minimis party Gresco Manufacturing, Inc. pursuant to section 122 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. 9622(h)(1) concerning the Carolina Steel Drug Superfund Site (Site) located in Rock Hill, York County, South Carolina. EPA will consider public comments on the proposed settlement for March 14, 2005. EPA may withdraw from or modify the proposed settlement should such comments disclose facts or considerations which indicate the proposed settlement is inappropriate, improper or inadequate. Copies of the proposed settlement are available from Ms. Paula V. Batchelor, U.S. EPA, Region 4, (WMD–SEIMB), 61 Forsyth Street, SW., Atlanta, Georgia 30303, (404) 562–8887, *Batchelor.Paula@EPA.gov.*

Written comments may be submitted to Ms. Batchelor within 30 calendar days of the date of this publication.

Dated: January 26, 2005.

Rosalind H. Brown,

Chief, Superfund Enforcement & Information Management Branch, Waste Management Division.

[FR Doc. 05–2613 Filed 2–9–05; 8:45 am]

BILLING CODE 6560–5O–M

FEDERAL COMMUNICATIONS COMMISSION

Sunshine Act Meeting; Open Commission Meeting Thursday, February 10, 2005

February 3, 2005.

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Thursday, February 10, 2005, which is scheduled to commence at 9:30 a.m. in Room TW–C305, at 445 12th Street, SW., Washington, DC.

Item No.	Bureau	Subject
1	Media	*Title:* Carriage of Digital Television Broadcast Signals: Amendments to part 76 of the Commission's Rules (CS Docket No. 98–120). *Summary:* The Commission will consider a Second Report and Order and First Order on Reconsideration concerning the carriage obligations of cable operators with respect to digital broadcasters.
2	Media	*Title:* WRGT Licensee, LLC for Assignment of License of WRGT–TV, Dayton, Ohio, to WRGT Licensee, LLC (New Nevada, LLC); WVAH Licensee, LLC for Assignment of License of WVAH–TV, Charleston, West Virginia, to WVAH Licensee, LLC (New Nevada, LLC); WTAT Licensee, LLC for Assignment of License of WTAT–TV, Charleston, South Carolina, to WTAT Licensee, LLC (New Nevada, LLC); Cunningham Broadcasting Corp. (Transferor) and Sinclair Acquisition XIII, Inc. (Transferee) for consent to transfer of control of television station WTTE–TV, Columbus, Ohio; Cunningham Broadcasting Corp. (Transferor) and Sinclair Acquisition XIII, Inc. (Transferee) For consent to transfer of control of television station WNUV–TV, Baltimore, Maryland. *Summary:* The Commission will consider a Memorandum Opinion and Order concerning an Application for Review filed by various licensee subsidiaries of Sinclair Broadcast Group, Inc. seeking review of a decision by the Media Bureau dismissing applications through which Sinclair sought to acquire television stations from the licensee subsidiaries of Cunningham Broadcasting Corporation.
3	Consumer & Governmental Affairs	*Title:* Rules and Regulations Implementing the Telephone Consumer Protection Act of 1991 (CG Docket No. 02–278). *Summary:* The Commission will consider a Second Order on Reconsideration addressing petitions for reconsideration filed regarding the national do-not-call registry and other TCPA rules.
4	Consumer & Governmental Affairs	*Title:* Rules and Regulations Implementing Minimum Customer Account Record Exchange Obligations on All Local and Interexchange Carriers (CG Docket No. 02–386).