UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 12 1992

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Reregistration Eligibility Document for Soap and Soap Salts Case/Chemical 4083/031801,079021 Caswell 701AB

FROM: Linda Kutney, Chemist 6-8-92
Science Administration Section
Science Analysis & Coordination Branch (SACB)
Health Effects Division (H7509C)

THROUGH: William Burnam, Chief
Science Analysis & Coordination Branch (SACB)

and

Penelope Fenner-Crisp, Ph.D., Director
Health Effects Division (H7509C) 6/12/92

TO: Veronica Dutch, Chemical Review Manager
Accelerate Reregistration Branch
Special Review and Reregistration Division (H7508W)

Attached is the Health Effects Division's position concerning the product chemistry and human health assessment for soap. This information is intended for use in the production of the Reregistration Eligibility Document (RED) for this compound. Included are the support chapters prepared by Pat McLaughlin (TOX II), Christina Swartz (CBRS), Barbara Madden (RD), and James Yowell (OREB).

We recommend that the ammonium salts be exempt from tolerance as well as the potassium salts, and that an appropriate change to the 40 CFR be made to include the ammonium salts as exempt from tolerance.

ATTACHMENTS

cc: Linda Deluise, PM-53, SRRD
Christina Swartz, CBRS
Sami Malak, RD
Jim Yowell, OREB
Pat McLaughlin, TB2
Barbara Madden, RD
Betsy Grimm, EFED
Caswell 701AB

A. IDENTIFICATION OF ACTIVE INGREDIENT

In the May 5, 1990 Federal Register publication of List D chemicals, Soap Salts, case 4083, included soap, oleic acid, ammonium oleate, sodium oleate, potassium laurate, potassium myristate, potassium oleate and potassium ricinoleate.

By definition "ordinary soap is a mixture of the sodium salts of various fatty acids of natural oils and fats. It is made by heating oils with caustic soda, salting out the soluble soap formed, and drawing off the dilute glycerol produced. Thus common soap is largely a mixture of the sodium salts of palmitic, stearic and oleic acids. The term soap is also applied to individual components such as sodium palmitate, sodium stearate, etc. In case some other metal or basic radical is present instead of sodium a modified term such as potash soap, calcium soap or amine soap is used." This latter category also includes ammonium soaps (ammonium salts of fatty acids).

Case 4083, soap and soap salts, is comprised of only two active ingredients which are currently associated with active product registrations. These two chemicals are (1) Ammonium Salts of [C8-C18 Saturated and C18 Unsaturated] Fatty Acids, including but not limited to Ammonium oleate; and (2) Potassium Salts of [C12-C18 Saturated] Fatty Acids, including but not limited to Potassium laurate, Potassium myristate, Potassium oleate, and Potassium ricinoleate. The remaining chemicals contained in this case (soap, as discussed below, oleic acid, and sodium oleate,) are no longer actively supported.

The technical grade of the active ingredient (TGAI) per se is not isolated during the manufacturing process. Given that the active ingredient is exempt from the requirement of a tolerance (40 CFR §180.1068), and is considered GRAS under 21 CFR §172.863, the Agency will not require generic data requirements to be satisfied using the TGAI as the test substance.

There are food uses for ammonium salts of fatty acids. For Guideline Reference Nos. 61-2(a), 61-2(b), and 62-1, the data from the EP will be translated to the TGAI, once the data to support the EP ~~has~~ have been evaluated and found acceptable. Guideline Ref. Nos. 61-1, 62-2, and 62-3 are product-specific requirements that will be addressed by RD after the RED has been issued. The Agency will not impose the requirements of 40 CFR §158.190, Guideline Ref. Nos. 63-2 through 63-13 using the TGAI, isolated/purified from the EP.

B. HUMAN HEALTH ASSESSMENT

1. Toxicology Data Base

The toxicological data base on soap and soap salts is adequate and will support reregistration eligibility.

a. Acute Toxicity

ACUTE TOXICITY DATA

TEST	EFFECT, CATEGORY
Oral LD50	IV
Dermal LD50	IV
Eye effects	Irritation
Skin effects	Mild - moderate irritation Non-sensitizing

Oral exposure to soaps is generally self-limiting because the taste of soap is easily recognized and unpleasant. The ammonium soap salts also have a notable ammonia odor that is limiting. Fatty acids such as oleic acid and related C_{12}--C_{18} fatty acids are generally considered to be of low toxicity by the oral route of exposure, and potassium salts of these fatty acids are not expected to be very toxic. The oral LD50 for oleic acid in rats was 74 g/kg (1).

On human skin, 2.5 mg of soap for 24 hours caused moderate irritation; and 10 mg of soap on rabbit skin caused mild irritation (1). On human skin, 11,800 mg of the potassium salt of palmitic acid was irritating (2). For the potassium salt of caprylic acid, 7320 mg was irritating on human skin (2). Stearic acid was mildly irritating to human skin when 75 mg was applied intermittently for 3 days (2). On rabbit skin, 500 mg of stearic acid applied for 24 hours was moderately irritating (2). Oleic acid was moderately irritating to human skin when 15 mg was applied intermittently for 3 days; and mildly irritating to rabbit skin when 500 mg was applied (1).

The potassium salt of oleic acid was irritating when 12 mg were placed in rabbit eyes (48 hours) (1, 2).

b. Metabolism

Fatty acids are normally metabolized by the cells, where they are oxidized to simple compounds for use as energy sources and as structural components utilized in all living cells. Potassium,

sodium and ammonium are normally part of the body's metabolism and electrolyte balance.

c. Reproduction and Developmental Toxicity

When given to mice on days 2-13 of pregnancy, the potassium salts of cocoa fatty acids were reported to have an effect on post-implantation mortality at 6 gm/kg, and to cause musculo-skeletal system abnormalities at 600 mg/kg (2).

d. Mutagenicity

DNA inhibition was reported with 600 umol/l of the sodium salt of caprylic acid, tested with guinea pig kidney cells (2). Unscheduled DNA synthesis was found in mouse cells with 35 mg/kg of oleic acid (1). Cytogenetic analysis was positive for 2500 ug/L of oleic acid with hamster fibroblasts and for 100 mg/L with Saccharomyces cerevisiae (1).

2. Dietary Exposure

There is a tolerance exemption for potassium oleate and related C_{12}-C_{18} fatty acid potassium salts [40 CFR §180.1068]. Salts of fatty acids (not including ammonium salts) are generally recognized as safe (GRAS) when used as "food grade" food additives [21 CFR §172.863] under the provisions of 21 CFR §172.5. Residue chemistry data requirements are not applicable due to the tolerance exemption. While there are registered food uses for ammonium salts of fatty acids, there is neither a tolerance nor a tolerance exemption for these salts under 40CFR Section 180.

3. Occupational and Residential Exposure

Those soaps manufactured specifically for insecticidal usage, (i.e., potassium salts of selected fatty acids) kill aphids, spider mites, mealybugs and whitefly on garden vegetables, shrubs and trees as well as household plants. Other uses include moss control in lawns as well as control of algae, lichens, and liverworts on roofs, walks, and fences, and in greenhouses. (3) Ammonium soaps of higher fatty acids are used as a rabbit and deer repellent on forage and grain crops, vegetables and field crops (unspecified), non-crop areas, nursery stock and ornamentals, flowers, roses, shrubs, fruit trees and vines.

The end use product labels for the potassium salts of fatty acids bear the signal word "CAUTION" and do not recommend any measures to reduce exposure. The end use product labels for the ammonium soaps of higher fatty acids bear the signal word "WARNING" and recommends that the user wear safety glasses because the products cause substantial but temporary eye injury: the products may also cause allergic skin reactions in some individuals; however, no measures are recommended to reduce skin exposure.

Exposure to users during application can be significant, but they have very low toxicological potential to harm humans and there is no reason to expect reasonable pesticide usage to constitute any hazard beyond ordinary exposure. End use product labeling for user protection, (i.e. protective eyeware) needs to be addressed on a product by product basis when labels are submitted. The toxicological data base on these soap salts is adequate and will support reregistration; therefore, the Agency is not asking for any new exposure data to be generated.

4. Risk Assessment

Soaps are mineral salts of naturally occurring fatty acids. The fatty acids are a significant part of the normal daily diet, for they occur in dietary lipids which usually constitute about 90 grams in a day's diet. EPA has stated that the residues from the pesticide uses are not likely to exceed levels of naturally occurring fatty acids in commonly eaten foods. The Food and Drug Administration lists salts of fatty acids, including the potassium salts, as additives that may be used as binders, emulsifiers, and anticaking agents in food (21 CFR 172.863). Also, that agency lists oleic acid derived from tall oil fatty acids (21 CFR 172.862), and lists fatty acids, including capric, caprylic, lauric, myristic, oleic, palmitic, and stearic acids, (21 CFR 172.860) as additives that may be safely used in foods. Stearic acid is generally recognized as safe for use as an ingredient in food (21 CFR 184.1090). A number of fatty acid salts are prior sanctioned for uses in food packaging materials (21 CFR 181).1

Because of the low (toxicology category IV) acute toxicity of

soap and soap salts via oral and dermal routes, and because residues from the pesticide uses are not likely to exceed levels of naturally occurring fatty acids in commonly eaten foods, and many of these compounds are generally recognized as safe for use as an ingredient in food, the data base on soap and soap salts is considered adequate and will support reregistraion eligibility.

BIBLIOGRAPHY

(1) Sax, N. I., and Lewis, R. J. SR, 1989. Dangerous Properties of Industrial Materials, 7th Edition. Van Nostrand Reinhold, New York.

(2) NIOSH, 1987. Registry of Toxic Effects of Chemical Substances, Washington, DC.

(3) Farm Chemicals Handbook 1985

ONE-LINERS

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

Subject: Toxicology Review for the Reregistration Eligibility Document on Soap and Soap Salts

To: Esther Saito, Section Head
Science Analysis & Coordination Branch
Health Effects Division

From: Patricia McLaughlin, Ph.D.
Toxicology II Branch, HED
E.A. Doyle for 4/22/92

Thru: Elizabeth Doyle, Ph.D., Head
Section IV, Toxicology II Branch, HED
E.A. Doyle 4/22/92

Marcia van Gemert, Ph.D., Chief
Toxicology II Branch, HED
mvangemert 4/22/92

Chemical: Soap Salts--Potassium and Ammonium Salts of Fatty Acids
Case number: 4083
Products: Insecticide sprays, deer and rabbit repellant, for food and non-food crops

Considerations: These are mineral salts of naturally occurring fatty acids. The fatty acids are a significant part of the normal daily diet, for they occur in dietary lipids which usually constitute about 90 g in a day's diet. EPA has stated that the residues from the pesticide uses are not likely to exceed levels of naturally occurring fatty acids in commonly eaten foods. The Food and Drug Administration lists salts of fatty acids, including the potassium salts, as additives that may be used as binders, emulsifiers, and anticaking agents in food (21 CFR 172.863). Also, that agency lists oleic acid derived from tall oil fatty acids (21 CFR 172.862), and lists fatty acids, including capric, caprylic, lauric, myristic, oleic, palmitic, and stearic acids, (21 CFR 172.860) as additives that may be safely used in foods. Stearic acid is generally recognized as safe for use as an ingredient in food (21 CFR 184.1090). A number of fatty acid salts are prior sanctioned for uses in food packaging materials (21 CFR 181).

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The toxicological data base on soap and soap salts is adequate and will support reregistration eligibility.

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b. Metabolism

Fatty acids are normally metabolized by the cells, where they are oxidized to simple compounds for use as energy sources and as structural components utilized in all living cells. Potassium, sodium and ammonium are normally part of the body's metabolism and electrolyte balance.

c. Reproduction and Developmental Toxicity

When given to mice on days 2-13 of pregnancy, the potassium salts of cocoa fatty acids were reported to have an effect on post-implantation mortality at 6 gm/kg, and to cause musculo-skeletal system abnormalities at 600 mg/kg (2).

d. Mutagenicity

DNA inhibition was reported with 600 umol/l of the sodium salt of caprylic acid, tested with guinea pig kidney cells (2). Unscheduled DNA synthesis was found in mouse cells with 35 mg/kg of oleic acid (1). Cytogenetic analysis was positive for 2500 ug/L of oleic acid with hamster fibroblasts and for 100 mg/L with Saccharomyces cerevisiae (1).

BIBLIOGRAPHY

(1) Sax, N. I., and Lewis, R. J. SR, 1989. Dangerous Properties of Industrial Materials, 7th Edition. Van Nostrand Reinhold, New York.

(2) NIOSH, 1987. Registry of Toxic Effects of Chemical Substances, Washington, DC.

ONE-LINERS

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES/HED/SACB
TOX ONELINERS

TOXCHEM NO. 701AB- Potassium salts of fatty acids FILE LAST PRINTED: 12/24/91

CITATION	MATERIAL	ACCESSION/ MRID NO.	RESULTS	TOX CAT	COREGRADE/ DOCUMENT#
81-1 Acute oral LD50 Species: rat ABS lab 16836; 12/18/80	Potassium salts of fatty acids 40.0% (42697-U)	244966	Insufficient dosage levels tested; therefore, LD50 could not be determined.		Supplementary 001229
81-1 Acute oral LD50 Species: rat N. Am. Sci Assoc.; 87T14875000 12/15/87	Secta Spray Veg. Oil soap insecticide conc. (35% Potassium salts of fatty acids 35% a.i.	408194-01	LD50 > 5.0 g/kg.	4	Guideline 008921
81-2 Acute Dermal LD50 Species: rabbit ABS lab 16836; 12/18/80	Potassium salts of fatty acids 40.0% (42697-U)	244966	LD50 > 2 g/kg, eschar formation, moderate erythema.	3	Guideline 001229
81-2 Acute Dermal LD50 Species: rabbit N. Am. Sci Assoc.; 87T14875000 12/08/87	Secta Spray Veg. Oil soap insecticide conc. (35% Potassium salts of fatty acids	408194-02	LD50 > 2.0 gm/kg.	3	Guideline 008921
81-3 Acute inhalation LC50 Species: rat (limit test) Products Safety Labs T-9485; 04/30/90	Secta Spray Veg. Oil soap insecticide conc. (35% Potassium salts of fatty acids	414751-03	LC50 > 3.39 mg/L.	3	Minimum 008921
81-4 Primary eye irritation Species: rabbit ABS lab 16836; 12/18/80	Potassium salts of fatty acids 40.0% (42697-U)	244966	Corneal opacity in 1/6 animals with clearing by day 31 (unwashed eyes) Redness, chemosis and discharge with clearing by day 10 (washed eyes)	3	Guideline 001229
81-4 Primary eye irritation Species: rabbit Midwest Research Inst. 7557-E; 8/31/83	Potassium salts 2%	251421	Day 1: 1/6 & 1/3 corneal opacity (sc.5); 2/6 & 2/3 redness (sc.1 &2) Day 2: clear.	3	Guideline 005058

TOXCHEM NO. 701AB- Potassium salts of fatty acids FILE LAST PRINTED: 12/24/91

CITATION	MATERIAL	ACCESSION/ MRID NO.	RESULTS	TOX CAT	COREGRADE/ DOCUMENT#
81-4 Primary eye irritation Species: rabbit N. Am. Sci Assoc.; 87T14875000 12/04/87	Secta Spray Veg. Oil soap insecticide conc. (35% Potassium salts of fatty acids	408194-03	Corneal involvement absent by day 7. Conjunctival irritation absent by day 7; (did not record discharge, did not score at 1 hr. & 4 days).	3	Minimum 008921
81-5 Primary dermal irritation Species: rabbit ABS lab 16836; 12/18/80	Potassium salts of fatty acids 40.0% (42697-U)	244966	PIS = 4.4/8.0. Severe erythema at both intact and abraded sites. Cracking and fissuring of epithelial layers. Blackened areas of skin.	1	Guideline 001229
81-5 Primary dermal irritation Species: rabbit Products Safety Labs T.9613; 04/30/90	Secta Spray Veg. Oil soap insecticide conc. (35% Potassium salts of fatty acids	414751-04	Symptoms cleared by day 14.	3	minimum 008921

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Kathy Rea 6-4-92
Barb Madden Rm225
305-5410
SOAPRD

SOAP SALTS - RED

March 19, 1992

This is a follow up to the meeting of March 4, 1992, attended by representatives of RD and SRRD, to determine which active ingredients would be included in the Soap Salts Reregistration Eligibility Document (RED), Reregistration Case Number 4083, and to alleviate any confusion which may exist regarding this issue. In the May 5, 1990 Federal Register publication of List D chemicals, Soap Salts, case 4083, included soap, oleic acid, ammonium oleate, sodium oleate, potassium laurate, potassium myristate, potassium oleate and potassium ricinoleate.

By definition "ordinary soap is a mixture of the sodium salts of various fatty acids of natural oils and fats. It is made by heating oils with caustic soda, salting out the soluble soap formed, and drawing off the dilute glycerol produced. Thus common soap is largely a mixture of the sodium salts of palmitic, stearic and oleic acids. The term soap is also applied to individual components such as sodium palmitate, sodium stearate, etc. **In case some other metal or basic radical is present instead of sodium a modified term such as potash soap, calcium soap or amine soap is used."**[1] This latter category also includes ammonium soaps (ammonium salts of fatty acids).

In a letter dated March 3, 1989, addressed to Mr. Frederick A. Provorny in regards to Safer, Inc., signed by Anne Lindsay, Director, Registration Division, the Agency stated "the Agency currently considers all potassium salts of fatty acids, and all combinations of these chemicals, to be a 'single active ingredient' for purposes of pesticide registration." (see attached)

At the March 4 meeting, it was determined that, of those chemicals included in Case 4083, only two active ingredients are currently associated with active product registrations. These two chemicals are (1) ammonium salts of [C_8-C_{18} saturated and C_{18} unsaturated] fatty acids, and (2) potassium salts of [C_{12}-C_{18} saturated] fatty acids. The remaining chemicals contained in this case (soap, as discussed below, oleic acid, and sodium oleate,) are no longer actively supported.

With the exception of one compound (ammonium oleate), a separate PC Code for the compounds included in the category "ammonium salts of fatty acids" did not exist prior to the meeting. As a result, those products which contained these

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[1]The Condensed Chemical Dictionary, 7th ed., Reinhold Publishing Co., 1966.

(1)

particular chemicals were coded as "soaps". It was determined that ammonium salts of fatty acids should be classified separately, and Mr. Cook has created a Shaunnessy Code for ammonium salts of fatty acids (031801), which will be included in Case 4083, and subsequently included in the RED for these chemicals. Those products which contain ammonium salts will be recoded by PPIS with this new PC Code.

Other than those products which contain ammonium salts, the remaining active ingredients which are coded as "soap" are associated with Antimicrobial products. As put forth in 40 CFR §153.139, the Agency has concluded that "soap" inclusively "has no independent pesticidal activity when included in antimicrobial products for the designated uses, and thus are properly classified as inert ingredients." Therefore, the active ingredient statement on the respective product labels and the corresponding CSF should be changed to reflect the reclassification of "soap" as an inert ingredient. This will be done separately from the RED process. Mr. Francis will notify the affected companies via Certified Mail concerning the active to inert status change. Those companies which respond appropriately will not be required to comply with the requirements of the RED.

If you have any questions please contact Barbara Madden at 305-5410 or Daphne Waldo at 305-6249.

Attending the March 4, 1992 meeting from SRRD was Linda Deluise and Veronica Dutch, from RD was Sami Malak(RSB), Walter Francis(APB), Rob Forrest, Daphne Waldo and Barbara Madden(IRB) and from PMSD was Charlie Cook.

cc: John Carley (PMSD/ISB)
Linda Deluise (SRRD/ARB)
Veronica Dutch (SRRD/ARB)
Bipin Gandhi (RD/RSB)
Tom Ellwanger (RD/RSB)
Susan Lewis (RD/FHB)
Joanne Miller (RD/FHB)
Gabe Patrick (BEAD/SSB)

The following is a list of the active products that should be included in the RED.

Active Ingredient	EPA Reg No.
4083-031801 Ammonium Salts of [C_8-C_{18} Saturated and C_{18} Unsaturated] Fatty Acids -including but not limited to: Ammonium oleate	400-383 400-429
4083-079021 Potassium Salts of [C_{12}-C_{18} Saturated] Fatty Acids -including but not limited to: Potassium laurate Potassium myristate Potassium oleate Potassium ricinoleate	239-2564 36488-31 36488-32 36488-33 36488-36 42697-1 42697-2 42697-6 42697-7 42697-10 42697-11 42697-13 42697-15 42687-16 42697-22 42697-33 42697-34 42697-35 53219-4 53219-5 53219-6 NC830011 7673-RN 7673-RR

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 26 1992

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: Soap. Potassium Salts of Fatty Acids (List D Reregistration Case No. 4083; Chemical ID No. 079021)/Ammonium Salts of Fatty Acids (List D Reregistration Case No. 4083; Chemical ID No. 031801). Chemistry Branch Input (Product and Residue Chemistry) to the Reregistration Eligibility Document (RED). CBRS Nos. 9081, 9082, 9084, 9089, 9094, and 9420. DP Barcode Nos. D171450, D171402, D171289, D171433, D171463, and D171442.

FROM: Christina B. Swartz, Chemist
Reregistration Section II
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

Christina B. Swartz

THRU: William J. Hazel, Ph.D., Section Head
Reregistration Section II
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

Edward Zager, for

TO: Linda Kutney
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

Due to confusion arising from the vague term "soap," The List D Reregistration Case No. 4083, soap salts, has been modified to include only two active ingredients, ammonium salts of fatty acids and potassium salts of fatty acids. Many of the active ingredients previously classified as soaps are currently being considered as largely inert ingredients of antimicrobial products. Ammonium salts of fatty acids have been assigned a new Chemical ID Number (031801), while the potassium salts of fatty acids retain the Chemical ID No. 079021. The chemical ID No. 079009, formerly used for "soap" should no longer be applied to active ingredients containing either potassium or ammonium salts of fatty acids.

CONCLUSIONS

The following conclusions pertaining to the residue and product chemistry considerations for the reregistration of products containing the active ingredients potassium and ammonium salts of fatty acids should be included in the HED input to the reregistration eligibility document:

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RESIDUE CHEMISTRY

There is a tolerance exemption for potassium oleate and related C_{12}-C_{18} fatty acid potassium salts [40 CFR §180.1068]. Salts of fatty acids (not including ammonium salts) are generally recognized as safe (GRAS) when used as "food grade" food additives [21 CFR §172.863] under the provisions of 21 CFR §172.5. Residue chemistry data requirements are not applicable due to the tolerance exemption. There are no registered food uses for ammonium salts of fatty acids and, hence, residue chemistry data are again inapplicable.

PRODUCT CHEMISTRY

Potassium Salts of Fatty Acids: List D Case No. 4083, ID No. 079021

The technical grade of the active ingredient (TGAI) per se is not isolated during the manufacturing process. Given that the active ingredient is exempt from the requirement of a tolerance (40 CFR §180.1068), and is considered GRAS under 21 CFR §172.863, the Agency will not require generic data requirements to be satisfied using the TGAI as the test substance. For Guideline Ref. Nos. 61-2(a), 61-2(b), and 62-1, the data will be translated from the MP to the TGAI, once the product chemistry data have been evaluated and found acceptable. Guideline Ref. Nos. 61-1, 62-2, and 62-3 are product-specific requirements that will be addressed by RD after the RED has been issued. The Agency recognizes that isolation of the TGAI from the MP, for use in satisfying Guideline Ref. Nos. 63-2 through 63-13, may impose an undue financial burden on the registrants, and hence will not require that these data be submitted. The appropriate data submitted in support of MPs and EPs will be considered acceptable to support the TGAI.

Ammonium Salts of Fatty Acids: List D Case No. 4083, ID No. 031801

There are no food uses for this chemical. For Guideline Reference Nos. 61-2(a), 61-2(b), and 62-1, the data from the EP will be translated to the TGAI, once the data to support the EP has been evaluated and found acceptable. Guideline Ref. Nos. 61-1, 62-2, and 62-3 are product-specific requirements that will be addressed by RD after the RED has been issued. Unless EEB/EFED determine that they need to know the physical and chemical characteristics of the TGAI for evaluation of the toxicity of ammonium salts of fatty acids to aquatic organisms, the Agency will not require that the requirements of 40 CFR §158.190, Guideline Ref. Nos. 63-2 through 63-13 be satisfied using the TGAI, isolated/purified from the EP.

DETAILED CONSIDERATIONS

PRODUCT CHEMISTRY

For active ingredients on FIFRA 88 Reregistration Lists B, C, and D, CBRS (Chemistry Branch II: Reregistration Support) evaluates product chemistry submissions for the Technical Grade of the Active Ingredient (TGAI), to ensure that the generic requirements of 40 CFR §158.150-190 are satisfied. Registration Division (RD) is responsible for evaluating product specific data submitted for manufacturing products (MPs) and End-Use Products (EPs). The potassium and ammonium salts of fatty acids present an unusual case because the TGAI, per se, is never isolated during the manufacturing process, which includes the incorporation of the active ingredients with water and other solvents to form the MP. Many of the MPs are simply concentrated solutions of soaps, which are then diluted to yield the EPs.

Potassium Salts of Fatty Acids: List D Case No. 4083, ID No. 079021

The active ingredient potassium salts of fatty acids is exempt from the requirement of a tolerance (40 CFR §180.1068), and is considered GRAS under 21 CFR §172.863. Conversations with E. Saito (SACB/HED) and B. Grim (EFED) have revealed that for the purposes of the toxicology evaluation and outstanding environmental fate/ecological effects concerns, the generic product chemistry data for the TGAI per se are not strictly required. For Guideline Reference Nos. 61-2(a), 61-2 (b), and 62-1, for which the test substance is both the MP and the TGAI, CBRS will translate the data from the MP to the TGAI, once the data to support the MP have been evaluated and found acceptable by RD.

In the case of active ingredients for which there is no TGAI isolated during the manufacturing process, CBRS has historically required registrants to submit data supporting the requirements of 40 CFR §158.190, Guideline Reference Nos. 63-2 to 63-13 (physical and chemical properties) using the TGAI, purified/isolated from the MP. CBRS would prefer that registrants submit 63-series data for the TGAI potassium salts of fatty acids, isolated by removal of the solvents/water incorporated into the MP during the manufacturing process. However, CBRS will not require that these data be submitted, taking into account the reasons outlined in the previous paragraph, in conjunction with the recognition that the active ingredient has been granted low volume/minor use status, indicating that the generation of such data may produce an undue financial burden on the registrants.

Safer, Inc.; CBRS Nos. 9081 and 9089

The RED review package received by CBRS contained data supporting the MP, Safer 49% Insecticidal Soap (EPA Reg. No. 42697-1), as well as two EPs, Safer House and Garden Insect Killer, and Safer Weed and Grass Killer.

The following MRIDs, pertaining to the MP (listed for each guideline reference for which they are applicable), were included in the CBRS review package:

61-1, 61-2, and 61-3:	MRID Nos. 94241004 and 94244001
62-2 and 62-3 (62-1 not submitted):	MRID Nos. 94241007 and 94244004
63-2 through 63-13:	MRID Nos. 94241011 and 94244005

In addition, the following MRIDs were submitted for the 2 EPs:

942410-01,-02,-03,-05,-06,-08,-09,-10,-47,-48

942440-02,-03,-22,-24

All of the above data packages (including those submitted in support of the MP) should be forwarded to RD for review according to the MP and EP product chemistry data requirements.

Mycogen Corporation, CBRS No. 9420

Mycogen corporation indicated in their Phase 2 Response Worksheet (Parts A and B) that they would rely upon data generated by Safer, Inc. Safer Correspondence regarding waiver requests and data gaps (Phase 2 and Phase 3) was resubmitted by Mycogen for Agency review. Mycogen is currently attempting to obtain a "me-too" registration for their product, M-Pede®. No action is required by CBRS at this time.

Attack Pesticides, CBRS Nos. 9082 and 9092

The product chemistry package sent to CBRS contains data supporting the Aphid Mite Attack insecticidal soap concentrate (25% ai), as well as 2 EPs, which are dilutions of the concentrate. The MRID Nos. included in the CBRS review package are as follows:

942400-01,-02, and -03; 942430-01,-02, and -03

These data packages should be forwarded to RD for review upon issuance of the RED. No action is required by CBRS at this time.

Chevron Corporation, CBRS No. 9084

Chevron's Orthomite Insecticidal Soap (EPA Reg. No. 239-2564) is an EP. The active ingredient, potassium salts of higher fatty acids is obtained from Norman Fox Co. CBRS did not receive a reregistration review package containing data for this registrant/producer. The

MRID Nos. found in the CBRS review package are as follows:

Series 61 MRID No. 94242001 (with Confidential Appendix), Phase 3 Summary

Series 62 MRID No. 94242002 (with Confidential Appendix), Phase 3 Summary

Series 63 MRID No. 94242003 (with Confidential Appendix), Phase 3 Summary

No action is required by CBRS at this time. The data should be forwarded to RD for review upon issuance of the RED.

Murphy-Phoenix Company, CBRS No. 9094

The Murphy-Phoenix Company is currently pursuing registration of an insecticidal soap concentrate (MP), as well as an end product, which is a dilution of the concentrate. The registrant has been informed by RD that they must comply with reregistration requirements. No action is required by CBRS at this time. The CBRS review package contained several studies, but the copies sent to CBRS did not have MRID Nos. on them.

Ammonium Salts of Fatty Acids: List D Case No. 4083, ID No. 031801

There is only one registrant supporting reregistration of products containing the active ingredient ammonium salts of fatty acids, and neither of the products is either a TGAI or manufacturing use only product. There are no food uses for this chemical. For Guideline Reference Nos. 61-2 (b), and 62-1, for which the test substance is both the EP and the TGAI, CBRS will translate the data from the EP to the TGAI, once the data to support the EP has been evaluated and found acceptable by RD. There are outstanding ecological effects concerns (personal communication, B. Grim, EFED) involving potential toxicity to aquatic invertebrates; potassium salts of fatty acids are toxic to aquatic invertebrates, but little is known about the toxicity of ammonium salts of fatty acids. The test substance used to satisfy Guideline Ref. Nos. 72-1 through 72-6 (40 CFR §158.490, aquatic organisms testing) is the TGAI. Unless EEB/EFED determine that they need to know the physical and chemical characteristics of the TGAI for evaluation of the toxicity of ammonium salts of fatty acids to aquatic organisms, CBRS will not require that the requirements of 40 CFR §158.190, Guideline Ref. Nos. 63-2 through 63-13 be satisfied using the TGAI, isolated/purified from the EP.

Uniroyal Corporation, CBRS No. 9093

Uniroyal has submitted product chemistry data to support reregistration of their EPs, Hinder (EPA Reg. No. 400-383) and Hinder H (EPA Reg. No. 400-429). The registrant has submitted product chemistry data for the two EPs under the following MRID Nos.:

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417671-01 through 417671-11

418059-01 through 418059-04

All of the above data packages should be forwarded to RD for review upon issuance of the RED. No action is required by CBRS at this time.

cc: CSwartz; WJHazel; List D Reregistration File; Circu; RF; SF; S. Malak, RD (H7505C); B. Madden, RD (H7505C); Betsy Grim, EFED (H7507C); C. Furlow (PIB/FOD).
H7509C:CSwartz:CM2:Rm #800D:703 305 5877:5/22/92

RDI:WJHazel:5/22/92 EZager:5/26/92

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 2 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Soap. Potassium Salts of Fatty Acids (List D Reregistration Case No. 4083; Chemical ID No. 079021)/Ammonium Salts of Fatty Acids (List D Reregistration Case No. 4083; Chemical ID No. 031801). Addendum to the Chemistry Branch Input (Product and Residue Chemistry) to the Reregistration Eligibility Document (RED). CBRS Nos. 9092, 9093, and 9421. DP Barcode Nos. D171297, D171031, and D174154.

FROM: Christina B. Swartz, Chemist
Reregistration Section II
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

THRU: William J. Hazel, Ph.D., Section Head
Reregistration Section II
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

TO: Linda Kutney
Science Analysis and Coordination Branch
Health Effects Division (H7509C)

CBRS would like to bring to your attention 3 errors in the Chemistry Branch input to the soap (ammonium and potassium salts of fatty acids) Reregistration Eligibility Document:

1. The CBRS Nos. 9092 and 9093 (DP Barcode Nos. D171297 and D171031) were omitted from the subject heading in the 5/26/92 CBRS memo (C. Swartz) containing the CBRS input to the soap RED; however, these data packages were discussed in the memo.

2. CBRS No. 9421 (DP Barcode No. D174154) should have been, but was not included in the product chemistry discussion under **ammonium salts of fatty acids (ID No. 031801)**. The data package contained MRID Nos. 421914-01,-02, and -03, and should also be forwarded to RD for review of the data applicable to the two Uniroyal EPs, following issuance of the RED. This omission does not affect the conclusions of the 5/26/92 memo.

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3. It has come to the attention of CBRS that there are food uses for products containing ammonium salts of fatty acids. This does not affect any of the product chemistry considerations in the CBRS memo of 5/26/92. However, the conclusions for residue chemistry considerations should be revised as follows:

   The sentence which states "There are no registered food uses for ammonium salts of fatty acids..." should be revised to state the following: "While there are registered food uses for ammonium salts of fatty acids, there is neither a tolerance nor a tolerance exemption for these salts under 40 CFR, §180. If there are no outstanding TOX considerations, a tolerance exemption for ammonium salts of fatty acids should be established under 40 CFR §180."

   If you need additional input, please advise.

cc: CSwartz; WJHazel; List D Reregistration File; Circu; RF; SF; S. Malak, RD (H7505C); B. Madden, RD (H7505C); Betsy Grim (EFED (H7507C); C. Furlow (PIB/FOD).

H7509C:CSwartz:CM2:Rm #810F:703 305 5877:5/27/92

RDI:WJHazel:5/28/92 MMetzger:6/2/92 EZager:6/2/92

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 8 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM:

Subject: Review of potential Occupational and Residential Exposure to Soaps for the Reregistration Eligibility Document (RED).

To: Esther Saito, Chief
Science Administration Section
Science Analysis & Coordination Branch (SACB)
Health Effects Division (H7509C)

From: James Yowell, Senior Scientist James Yowell
Reregistration Section II
Occupational and Residential Exposure Branch
Health Effects Division (H7509C)

Thru: Alan Nielsen, Chief Al Nielsen
Reregistration Section II
Occupational and Residential Exposure Branch
Health Effects Division (H7509C)

Thru: Larry Dorsey, Acting Chief Larry Dorsey 6/9/92
Occupational and Residential Exposure Branch
Health Effects Division

Chemical: Soap Salts

Case#: 4083

Chemical#: 079095, 079009, and 079021

Company: 000239 Chevron Chemical Company
000400 Uniroyal Chemical Company, Inc.
Murphy
042697 Safer, Inc.
036488 Attack Pesticides
Mycogen Corporation

Defer to:
_____ **Biological Analysis Branch/BEAD**
_____ **Accelerated Reregistration Branch/SRRD**
_____ **TB-Insecticide/Rodenticide Support Section**
_____ **TB-Herbicide/Fungicide/Antimicrobial**

OCCUPATIONAL AND RESIDENTIAL EXPOSURE

Based on a limited number of labels (239-2564, 42697-01, 400-363, and 400-429) provided by Tox Branch II, soap salts are registered in the following forms and use patterns:

1) Potassium salts of fatty acids are used on vegetables up to the day of harvest, indoor plants (unspecified), and unspecified domestic dwellings (around the home). These products are applied by spray bottles or hand held sprayers. There is a 49.0% a.i. (packaged in an 8 ounce container and mixed with water) liquid formulation and a 2.0% a.i. (packaged in a 16 ounce container and is in ready-to-use form) liquid formulation.

2) Ammonium soaps of higher fatty acids are used as a rabbit and deer repellent on forage and grain crops, vegetables and field crops (unspecified), non-crop areas, nursery stock and ornamentals, flowers, roses, shrubs, fruit trees and vines. These products may be applied by ground or aerial sprays up to the day of harvest. There are two 15.0% a.i. liquid formulations, one is packaged in a one gallon container and the other is unspecified.

Examples of existing label limitations are as follows:

The end use product labels for the potassium salts of fatty acids bear the signal word "CAUTION" and do not recommend any measures to reduce exposure.

The end use product labels for the ammonium soaps of higher fatty acids bear the signal word "WARNING" and recommends that the user wear safety glasses because the products cause substantial but temporary eye injury: the products may also cause allergic skin reactions in some individuals, however, no measures are recommended to reduce skin exposure.

Exposure to users during application can be significant, but there is no reason to expect reasonable pesticide usage to constitute any hazard beyond ordinary exposure. End use product labeling for user protection; i.e. protective eyeware needs to be addressed on a product by product basis when labels are submitted. The toxicological data base on these soap salts is adequate and will support reregistration therefore, OREB is not asking for any new exposure data to be generated.

cc: James Yowell/OREB
Circulation
Pat McLaughlin/Tox II
Correspondence
Chemical File