



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

201-15579

JUN 23 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Melvin H. Kurtz
Vice President - Law
Unilever Home & Personal Care - USA
33 Benedict Place
Greenwich, Connecticut 06830

01 SEP -9 PM 2:36

RECEIVED

Dear Mr. Kurtz:

Thank you for your letter dated November 29, 1999, regarding the U.S. Environmental Protection Agency's (EPA) High Production Volume (HPV) Challenge Program. I apologize for the lengthy delay in responding to your request.

Your letter requested that the Agency remove Sodium Cocoyl Isethionate (CAS No. 61789-32-0), and Sodium Isethionate (CAS No. 15620-02-1), from the HPV Challenge Program Chemical List because they were reported in error to the EPA under the 1990 and 1994 Inventory Update Rule (IUR) reporting cycles. Our records show that the correct CAS No. for Sodium Isethionate is 1562-00-1, which will be used in the remainder of this response. You state in your letter that Unilever, BASF, and Clariant use these chemicals mostly for cosmetic wash products which are regulated by the Food and Drug Administration (FDA). You note that "uses outside of the personal cleaning areas are significantly less than one million pounds per year and, therefore, are well under the high production volume threshold of one million pounds per year."

In your letter, you have identified CAS No. 61789-32-0 as Sodium Cocoyl Isethionate. The chemical name associated with this CAS No., as listed on our HPV Chemical List, is Fatty acids, coco, 2-sulfoethyl esters, sodium salts. EPA does not consider Sodium Cocoyl Isethionate to be an acceptable synonym for Fatty acids, coco, 2-sulfoethyl esters, sodium salts. Because of this discrepancy in the chemical name, EPA encourages Unilever to re-evaluate its reporting under the IUR. Since your letter states that Unilever, BASF, and Clariant produce these chemicals for uses regulated under the FDA, EPA recommends each company amend their IUR reports to reflect accurate production volumes for the non-FDA uses.

As you know, EPA posted draft guidance on procedures for removing chemicals that are no longer HPV from the scope of the voluntary HPV Challenge Program on its Chemical Right-to-Know (ChemRTK) website (www.epa.gov/chemrtk) in March 1999. Based on our review of the most up-to-date Inventory Update Rule (IUR) reporting for years 1998 and 2002, EPA has

determined that Sodium Cocoyl Isethionate [*sic*] (CAS No. 61789-32-0) and Sodium Isethionate (CAS No. 1562-00-1) **do not meet** the no longer HPV criteria.

It is EPA's position that chemicals tested and approved under other Federal agency programs may contain data gaps in areas which may not be germane to other regulated uses (e.g., environmental fate and environmental toxicity), but which are germane to EPA concerns and are elements of the HPV Challenge Program. Furthermore, exposure scenarios may be different and may have the potential to cause adverse impacts on health or the environment. In addition, the data supporting the regulated use of chemicals reviewed by other Federal agencies may not be publicly available because of confidentiality claims. A manufacturer that submitted data under one program, however, could submit that same information to the EPA through the HPV Challenge Program in the form of robust summaries and thus allow it to become public.

We will post your letter, accompanied by our reply, on the ChemRTK website as soon as possible. Should you have any questions pertaining to this response, please contact Diane Sheridan at (202) 564-4770. If you have general questions concerning the HPV Challenge Program, please submit them through the ChemRTK website comment button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached via e-mail at tsc-hotline@epa.gov.

Sincerely,

Wardner G. Penberthy
Acting Director
Chemical Control Division

cc: AR201



Unilever

201-15578

Melvin H. Kurtz
Vice President - Law

November 29, 1999

Mr. Ward Pemberthy
Associate Director of the Chemical Control Division
Mail Code 7405
Environmental Protection Agency
401 M Street SW
Washington D.C. 20460

Re: Sodium Cocoyl Isethionate (CAS number 61789320),
Sodium Isethionate (CAS number 15620021)

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Dear Mr. Pemberthy:

I am confirming our telephone conversation wherein I advised you that we are sending you a written explanation of why Sodium Cocoyl Isethionate (hereinafter SCI) and Sodium Isethionate (hereinafter SI) should not have been included in the list of high production volume chemicals reported in 1990 and 1994, and subject to the Toxic Substance Control Act.

Lever Brothers Co., a trading name of Conopco, Inc., which is a subsidiary of Unilever United States, Inc., is the largest manufacturer of SCI. All of the SCI manufactured by Lever Brothers Co., which is produced from SI, is used in its cosmetic wash products which are and have been regulated by the Food and Drug Administration ("FDA"), and lawfully sold pursuant to FDA regulations and requirements. These products have been used in body washes, shampoos and personal wash bars since the early '60s. As I am sure you are aware, the food and drug laws do not permit the sale of any cosmetic that contains any poisonous or deleterious substance which may injure consumers. Our company takes all the necessary steps to ensure that its products meet these requirements. The company also has available environmental and safety toxicity data for SCI.

Since all the SCI manufactured by Lever Brothers Co. is incorporated in products regulated by the Food and Drug Administration, it is not included in the definition of chemical substance as defined by the Toxic Substance Control Act. Specifically, 15 USC Section 2602(B)(vi) which excludes any food, food additive, cosmetic, or device, as such terms are defined in Section 201 of the Federal Food, Drug and Cosmetic Act, when manufactured, processed, or distributed in commerce for use as a drug or cosmetic. Since the chemicals are used solely for these purposes, it is clear that they should never have been reported in 1990 and 1994, and we regret any inconvenience this may have caused the Environmental Protection Agency.

Unilever Home & Personal Care - USA

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Telephone (203) 625-1425

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We have also checked with suppliers of SI and SCI and they have advised us that they almost exclusively sell these materials for personal cleaning applications. Uses outside of the personal cleaning areas are significantly less than one million pounds per year and, therefore, are well under the high production volume threshold of one million pounds per year.

I am enclosing a letter from Clariant Corporation, the largest producer of SI and a major producer of SCI, in which they explain that sales or consumption of SI and SCI, outside of personal care and personal cleaning applications, are significantly less than one million pounds per year.

I am also enclosing a letter from BASF who have also advised that their sales of SCI are primarily used in personal cleaning applications and are significantly less than one million pounds per year for use for other purposes. Therefore, even with the combined sales and distribution from all manufacturers of SI and SCI for non-cosmetic uses, the threshold of one million pounds per year would not be reached.

For the aforesaid reasons, Conopco, Inc. believes that the presence of SI and SCI on the list of High Production Volume Chemicals Challenge Program is in error and we respectfully request the removal of these chemicals from the High Production Volume Challenge Program.

If you have any questions concerning this matter, please do not hesitate to contact me at 203-625-1425.

Sincerely

Melvin H. Kurtz

MHK:mlh
Enclosures

cc: Keith Cronin - Environmental Protection Agency
Ronald Soiefer - Unilever United States, Inc.

Clariant Corporation

4331 Chesapeake Drive
Charlotte, NC 28216-3410
800.538.8397

Clariant

Mr. Melvin H. Kurtz
Unilever H&PC USA
33 Benedict Place
Greenwich, CT 06830

MELVIN H. KURTZ
NOV 05 1999

October 22, 1999

Dear Mr. Kurtz,

As we discussed, Clariant Corp. is the largest producer of Sodium Isethionate (SI) (sold under the trade name Hostapon® SI) in the US. We are also a major producer of its most important chemical derivative, Sodium Cocoyl Isethionate (SCI) (sold under the trade name Hostapon® SCI). Most of the SI produced in the US is derivitized into SCI.

Our knowledge of the domestic and worldwide market for these products is that, with very few exceptions, SI and SCI are used in personal care and personal cleansing applications. The most important application is in personal cleansing bars, but the products are being incorporated also into liquid personal care and liquid personal cleansing formulations.

Clariant Corporation's sales or consumption of SI and SCI outside of personal care (including personal cleansing bars) and personal cleansing applications are significantly less than 1,000,000 lb. per year.

Sincerely,

Mark N. Rhines
Director of Marketing, Surfactants Division

November 30, 1999

Mr. Melvin Kurtz
Unilever HPC USA
33 Benedict Pl.
Greenwich, CT, 06836

Dear Mel;

Per our phone conversation this letter confirms the uses of the Jordapon line of Sodium Cocoyl Isethionates to be primarily for personal wash applications. These applications include; Syndet cleansing bars, Combo (mixed synthetic and Soap) cleansing bars, Shower gels, Body washes, Shampoos, etc..

Very little Sodium Cocoyl Isethionate is sold for other, non-personal care applications. While the exact sales are confidential, it can clearly be stated that the total sold into those non-personal wash applications are more than an order of magnitude less than the threshold 1 million lbs. per year.

Best regards,

Product Manager, BASF Cosmetic Chemicals