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201-16599

Jeffrey Taylor/DC/USEPA/US
05/16/2007 02:11 PM

To NCIC HPV@EPA
cc
bcc
Subject Fw: SESC Submission of HPV Challenge Documents

Hi NCIC,

Just making sure that you received David Kent's original email on 11/27/06 (at the very bottom of this email), as well as his email today (below) asking whether the original email slipped through the cracks.

Thanks,
Jeff

Jeffrey A. Taylor
U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
Chemical Control Division
EPA East -- Room 4410-H, Mail Code 7405M
1200 Penn Ave NW, Washington, DC 20004
Tel (202) 564-8828, Fax (202) 564-4775

----- Forwarded by Jeffrey Taylor/DC/USEPA/US on 05/16/2007 02:08 PM -----

"Kent, David"
<Kent@khlaw.com>
05/16/2007 01:49 PM

To NCIC OPPT@EPA, Rtk Chem@EPA, Diane Sheridan/DC/USEPA/US@EPA, Mark Townsend/DC/USEPA/US@EPA, Jeffrey Taylor/DC/USEPA/US@EPA
cc
Subject FW: SESC Submission of HPV Challenge Documents

Mark and Jeff

The SESC coalition submitted the email and attached documents below on November 27, 2006 in support of the HPV Challenge Program for CAS #61789-32-0 and CAS #1562-00-1. However, I still have not seen the documents posted on EPA's HPV web site.

Can you please check to make sure these didn't slip through the cracks and make sure they are posted? We would like to finalize the documents as soon as possible.

Thanks for your help. Very much appreciated.

David J. Kent

Staff Scientist

tel: 202.434.4221 | fax: 202.434.4646 | kent@khlaw.com

1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Kent, David
Sent: Monday, November 27, 2006 1:23 PM
To: 'oppt.ncic@epa.gov'; 'chem.rtk@epa.gov'; 'sheridan.diane@epa.gov'; 'townsend.mark@epa.gov'
Cc: 'taylor.jeffrey@epa.gov'
Subject: SESC Submission of HPV Challenge Documents
Importance: High

Dear Administrator Johnson et al.

<<DEFI to EPA by SESC 11-27-2006.pdf>> <<Final SCI Assessment Plan 11-24-06.pdf>> <<Final SCI Robust Summaries 11-24-06.pdf>> <<Final SI Assessment Plan 11-24-06.pdf>> <<Final SI Robust Summaries 11-24-06.pdf>>

Attached are five documents to support the Sodium Ethyl Sulfonates Coalition's (SESC) voluntary commitment to provide the available health and safety data for CAS #61789-32-0 and CAS #1562-00-1. The five documents, all in PDF format, are:

1) A cover letter

2) An assessment plan document for CAS #61789-32-0

3) A robust summary document for CAS #61789-32-0

4) An assessment plan document for CAS #1562-00-1

5) A robust summary document for CAS #1562-00-1

These documents summarize the available data and demonstrate the low hazard potential for these two chemicals.

Please contact me should you have any questions or comments on the attached documents. Also, please confirm receipt and provide an estimated time frame that you expected the documents to be posted on EPA's HPV Challenge web site.

Thank you for the opportunity to provide this information.

Regards,

David J. Kent

Staff Scientist

tel: 202.434.4221 | fax: 202.434.4646 | kent@khlaw.com

1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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Final SI Robust Summaries 11-24-06.pdf

201-16599

Sodium Ethyl Sulfonates Coalition

RECEIVED
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2007 JUN 21 AM 11:45

November 27, 2006

Steven L. Johnson, Administrator
US Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116
Attention: Chemical Right-to-Know Program
ncic_oppt@epa.gov; chem.rtk@epa.gov

Re: HPV Challenge Submission for CAS #61789-32-0 and CAS #1562-00-1

Dear Administrator Johnson:

The Sodium Ethyl Sulfonates Coalition (SESC) is pleased to submit the accompanying assessment plans and robust summary documents for the two chemicals SESC has sponsored under the voluntary USEPA HPV Chemical Challenge program. The two chemicals are CAS #61789-32-0, known as Fatty acids, coco, 2-sulfoethyl esters, sodium salts (commonly called sodium cocoyl isethionate); and CAS #1562-00-1, known as Ethanesulfonic acid, 2-hydroxy-, monosodium salt (commonly called sodium isethionate).

These documents (in PDF format) have been sent electronically to the following email addresses:

Opt.ncic@epa.gov
Chem.rtk@epa.gov
Sheridan.Diane@epa.gov
Townsend.Mark@epa.gov

Any comments and questions should be sent David J. Kent, the SESC designated contact person, at Keller and Heckman LLP (202-434-4221; kent@khlaw.com; 1001 G Street, NW, Washington DC 20001).

Sincerely,

David Mallon, Coalition Administrator
Sodium Ethyl Sulfonates Coalition

Cc: David J. Kent, Keller and Heckman LLP

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2007 MAY 13 AM 7:22

201-16599A

Assessment Plan for Ethanesulfonic Acid, 2-Hydroxy-, Monosodium Salt (Sodium Isethionate, CAS #1562-00-1) in Accordance with the USEPA High Production Volume Chemical Challenge Program

Prepared for:

The Sodium Ethyl Sulfonates Coalition

November 24, 2006

Keller and Heckman LLP

1001 G Street, NW
Washington, DC 20001
www.khlaw.com

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EXECUTIVE SUMMARY

The Sodium Ethyl Sulfonates Coalition (SESC) is sponsoring ethanesulfonic acid, 2-hydroxy-, monosodium salt, commonly called sodium isethionate (SI), in the US High Production Volume (HPV) Challenge program. SI is primarily used in detergent bar soaps and body washes and as an intermediate in the production of sodium cocoyl isethionate (SCI). Most of the production of SI is used as an intermediate in the production of SCI, and as such is primarily for uses regulated by the US Food and Drug Association (FDA). The SESC assembled and reviewed the available public and private toxicological data, and developed an assessment plan for the sponsored chemical.

SI is highly soluble in water and has a very low affinity for bioaccumulation. SI is readily biodegradable, exhibiting 63-100% degradation in 10-28 days. SI was found to be non-toxic to aquatic organisms. No mortality or other significant effects were observed in several acute toxicity tests conducted on fish, *Daphnia*, and algal species. SI also exhibited no apparent toxicity in mammalian toxicity studies. It is not irritating to the skin or eyes of rabbits, and is not mutagenic to *Salmonella* or *E. coli* in genotoxicity studies. No data are available for the skin sensitization, repeated dose, reproductive and developmental toxicity endpoints. Human studies illustrate that SI is used in consumer products with no reported effects. When testing SI as a component of products containing both SCI and SI, no observable effects were also shown. Potential read across to the available repeated dose data for SCI (via oral and dermal routes) would indicate no significant mammalian toxicity is likely following repeated exposure to SI.

Manufacturing and processing of sodium isethionate takes place in controlled work environments that are designed to minimize worker and environmental exposure. Workers wear standard personal protective equipment and local exhaust ventilation to control vapor, mist or dust generation is recommended. In addition, engineering controls are in place at all manufacturing sites to minimize releases to the environment. Consumer exposure to diluted SI is primarily via the dermal route as an ingredient in moisturizing soap bars, other skin cleansers and personal wash products, at levels ranging from 0 to 15%. SI is much milder than soap to the skin, and is rinsed off immediately in the act of washing due to its high water solubility and low skin penetration potential. Therefore, consumer exposure to SI is not considered to be a significant concern.

Based on the availability of data and the lack of apparent toxicity, sodium isethionate is considered to be of low concern and no further testing is being proposed at this time.

INTRODUCTION

The High Production Volume (HPV) Challenge Program is a voluntary initiative of the US chemical industry to complete hazard data profiles for approximately 2800 HPV chemicals as identified on the US Environmental Protection Agency's (USEPA) 1990 Toxic Substances Control Act (TSCA) Inventory Update Rule (IUR). In the US, HPV chemicals are those that are manufactured or imported in quantities greater than 1 million pounds per year. The hazard data to be provided in the program are those that meet the requirements of the Screening Information Data Set (SIDS) Program (OECD 1997). SIDS, which has been internationally agreed to by member countries of the Organization for Economic Cooperation and Development (OECD), provides the basic screening data needed for an initial assessment of the physical-chemical properties, environmental fate, and adverse human and environmental effects of chemicals. The information for completing the SIDS can come from existing data or may be generated as part of the HPV Challenge Program. Once the available studies are identified or conducted, "robust summaries" are prepared.

The USEPA, industry, and non-governmental organizations (NGOs) are unified in their commitment to minimize the numbers of animals tested in the HPV Challenge Program whenever it is scientifically justifiable (USEPA 1999a, 2000). Therefore, this test plan evaluates all of the existing data for the sponsored chemical in an effort to adequately characterize the health and environmental hazard while reducing the number of animals required for testing.

The Sodium Ethyl Sulfonates Coalition (SESC) has agreed to assemble and review available public and private toxicological data, develop and provide an assessment plan for the sponsored chemical and conduct additional research, including testing when necessary, for ethanesulfonic acid, 2-hydroxy-, monosodium salt, which is more commonly and hereafter called in this report, sodium isethionate (SI). SI is a surfactant-cleansing agent used in synthetic soaps. The SESC is comprised of the following member companies:

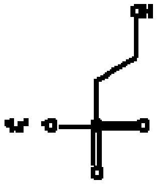
BASF Corporation
Clariant Corporation
Huntsman Petroleum Corporation
Unilever Home and Personal Care

This assessment plan is the result of the SESC's efforts and provides a summary and analysis of the available data, and identifies any data gaps in the SIDS data profile. The first section of this assessment plan provides an identification of the sponsored chemical, including its structure, production process, and use pattern. Following that are sections on the process used to collect the unpublished and published data and how those data were evaluated for quality and acceptability. This is followed by a discussion of the physical-chemical properties, environmental fate and transport, ecotoxicity and mammalian toxicity data as summarized in the accompanying robust summary document. Finally, conclusions regarding data availability and identification of data gaps in the SIDS profiles for the sponsored chemical are presented.

IDENTIFICATION OF SPONSORED CHEMICAL

A. Chemical Structure

The chemical being sponsored by the SESC is Sodium Isethionate (CAS #1562-00-1). Sodium isethionate (SI) is the sodium salt of isethionic acid and functions as a surfactant and lathering agent in synthetic cleansing bars and detergents. SI is also known by several synonyms, including: ethanesulfonic acid, 2-hydroxy-, monosodium salt; 2-hydroxyethanesulfonic acid, sodium salt; isethionic acid, sodium salt; and sodium hydroxyethylsulfonate. The basic chemical formula for SI is $C_2H_5NaO_4S$, and can be represented by:



B. Production Process

SI is prepared in a relatively simple two step process (Friedman 2004). The first step involves reacting sodium hydroxide (NaOH) with sulfur dioxide (SO_2) to form sodium bisulfite ($NaHSO_3$). The second step reacts the sodium bisulfite with ethylene oxide to form sodium isethionate ($HO - CH_2 - CH_2 - SO_3Na$). SI is normally provided with a nominal active content of 57.0% in water to manufacturers of sodium cocoyl isethionate, where it may be concentrated further.

C. Use Patterns and Exposure Potential

SI is primarily used in synthetic and combination detergent bar soaps and as an intermediate in the production of sodium cocoyl isethionate (SCI). Other uses of SI include skin cleansing and personal washing agents, cosmetics, intermediates, and ingredients in shampoo and bubble baths. SI and SCI are milder on the skin than soap and are non-drying. They offer a dense lather in addition to the lather made by the soap. SI works equally well in both hard and soft water (Friedman 2004). Most of the production of SI is used as an intermediate in the production of SCI for use directly in personal wash products and as such is primarily for uses regulated by the US Food and Drug Administration (FDA).

Manufacturing and processing of sodium isethionate takes place in controlled work environments that are designed to minimize worker and environmental exposure. Workers wear standard personal protective equipment, which may include chemical-type safety goggles or glasses, chemical-resistant safety shoes, impervious gloves, and protective clothing designed to minimize skin contact. Local exhaust ventilation to control vapor, mist or dust generation is recommended. If needed, mechanical ventilation and/or use of masks and respirators may be used. Safety showers and eyewash stations are provided in all areas where the material is handled. In addition, extensive engineering controls are in place at all manufacturing sites to minimize releases to the environment.

Consumer exposure to SI is primarily dermal as a diluted material in personal wash products. SI is used as an ingredient in moisturizing soap bars, and other skin cleansers and skin detergents, at levels ranging from 0 to 15%. In these uses, SI is one component of a multi-component formulation that includes other surfactants (e.g., SCI), free fatty acids, fragrances, and water. SI is much milder than soap to the skin, and is rinsed off immediately in the act of washing. Therefore, consumer exposure to SI is not considered to be a significant concern.

Based on the use patterns described above, exposure to SI is expected to be adequately controlled and not of concern for workers, consumers, and the environment.

COLLECTION OF UNPUBLISHED AND PUBLISHED DATA

Coalition member companies contributed in-house studies of physical-chemical properties, environmental fate and transport, ecotoxicity, and mammalian toxicity for the chemicals and mixtures in the category. To supplement the industry data, literature searches were conducted of on-line databases (*e.g.*, Hazardous Substances Databank [HSDB], Registry of Toxic Effects of Chemical Substances [RTECS], and the USEPA's ECOTOX database), standard scientific data compendia (*e.g.*, *CRC Handbook of Chemistry and Physics* and *The Merck Index*), and other published sources (*e.g.*, International Uniform Chemical Information Database [IUCLID]). The sum total of the in-house studies, reference books, and literature searches of on-line databases was the identification of a substantial amount of available data for the sponsored chemical.

EVALUATION OF DATA FOR QUALITY AND ACCEPTABILITY

The collected data were reviewed for quality and acceptability following the USEPA and OECD SIDS guidance (USEPA 1999b; OECD 1997) and the systematic approach described by Klimisch et al. (1997). These methods include consideration of the reliability, relevance and adequacy of the data in evaluating their usefulness for hazard assessment purposes. The Klimisch et al. (1997) approach specifies four categories of reliability for describing data adequacy. These are:

1. **Reliable without Restriction:** Includes studies or data complying with Good Laboratory Practice (GLP) procedures, or with valid and/or internationally accepted testing guidelines, or in which the test parameters are documented and comparable to these guidelines.

2. **Reliable with Restrictions:** Includes studies or data in which test parameters are documented but vary slightly from testing guidelines.

3. **Not Reliable:** Includes studies or data in which there are interferences, or that use non-relevant organisms or exposure routes, or which were carried out using unacceptable methods, or where documentation is insufficient.

4. **Not Assignable:** Includes studies or data in which insufficient detail is reported to assign a rating, *e.g.*, listed in abstracts or secondary literature.

Only those studies which are deemed reliable for the current HPV Challenge Program purposes are included in the data set for this assessment plan. Reliable studies include both categories rated 1 (Reliable without restriction) and 2 (Reliable with restrictions). Studies rated 3 (Not reliable) were not used. Studies rated 4 (Not assignable) were used when professional judgment deemed it appropriate as part of a weight-of-evidence approach.

Much of the available data were from study reports conducted by either outside contract laboratories or in-house industry laboratories. These study reports followed standard procedures for testing of physical-chemical properties, environmental fate and transport, aquatic toxicity, and mammalian toxicity. Some of the most recent studies were conducted under GLP provisions. In addition, some data were obtained from the published, peer-reviewed, scientific literature. Finally, some data were gleaned from the initial IUCLID data set prepared in 2000. Where the original study reports from the IUCLID data set could be obtained these were reviewed directly and summarized. Some of the reports cited in the IUCLID document could not be located; these data were included as appropriate and the IUCLID data set cited accordingly. Klimisch scores of 4 (not assignable) were given for data cited in IUCLID but not directly obtainable. Reliable data from all sources were incorporated into the data set as appropriate. Overall, a substantial amount of data are available for sodium isethionate.

Robust summaries were prepared according to the format recommended by the USEPA (1999c) and OECD (1997). These summaries present the salient information from each of the reliable studies. All of the summaries are collected into a dossier. The robust summary dossier for SI is attached as an appendix and should be used in conjunction with this assessment plan.

SUMMARY OF AVAILABLE DATA

The following discussion reviews the available data identified for each of the four major data areas: physical-chemical properties, environmental fate and transport, ecotoxicity, and mammalian toxicity.

Physical-Chemical Properties

Physical-chemical property data are available primarily from the IUCLID 2000 data set for sodium isethionate and from estimations made using the USEPA EPI Suite software. These data are summarized in Table 1:

Table 1. Physical-Chemical Properties

Endpoint	Value	Source	Reliability
Melting Point	193-196°C	IUCLID 2000	4
	214.41°C	EPI Suite	2
	191-194°C	Chemfinder.com	4
Boiling Point	>230°C	IUCLID 2000	4
	503.88°C	EPI Suite	2
Density	800-1000 kg/m^3	IUCLID 2000	4
Vapor Pressure	1.37×10^{-12} mm Hg at 25°C	EPI Suite	2
Partition Coefficient (Log K_{ow})	-5.50 at 25°C	EPI Suite	2
Water Solubility	1000 g/L at 25°C	EPI Suite	2
	650 g/L at 20°C	IUCLID 2000	4

Melting and boiling point data were presented in the IUCLID 2000 data set and were also estimated using EPI Suite. The data are consistent with a material that is a solid at room temperature. Vapor pressure data were estimated with EPI Suite and indicate that sodium isethionate would not be expected to volatilize significantly. The EPI Suite estimation of the log K_{ow} value indicates that sodium isethionate is unlikely to bioaccumulate. Finally, the IUCLID data set data and EPI Suite estimations confirm that sodium isethionate is very highly soluble in water.

Based on the availability of IUCLID data set data and EPI Suite estimations, no further testing for physical-chemical properties is being proposed at this time.

Environmental Fate and Transport

Environmental fate data are important for demonstrating the primary mechanism or mechanisms of degradation and how a material's properties affect its transport in the environment. For organic chemicals, fate is generally a function of the breakdown of compounds into smaller constituents by biological degradation. Other breakdown mechanisms that may be important are photolysis and hydrolysis. These breakdown mechanisms are necessarily dependent on what environmental compartment (air, water, soil, sediment) to which the chemicals are distributed. Fugacity modeling can be used to estimate the relative percentage of chemicals that will partition to various compartments at steady state. The results of the Level III fugacity modeling using EPI Suite using its standard estimated input parameters are shown in Table 2. EPI Suite utilizes input values for relevant physicochemical parameters from its resident database, which has undergone extensive peer review and is accessed by input of the CAS number.

Table 2. Environmental Distribution of Sodium Isethionate Based on EQC Modeling

Environmental Compartment	Sodium Isethionate
Air	0.173%
Water	34.7%
Soil	65.1%
Sediment	0.06%

Based on physical-chemical properties, the fugacity modeling predicts that most of the sponsored chemical will partition to the soil and water. Very little is expected to partition to the air or sediment. It should be noted that these results are estimates of theoretical distribution in the environment. Actual fate and distribution in the environment would be a function of both the physical-chemical properties and the use pattern of sodium isethionate.

The atmospheric oxidation potential of sodium isethionate was estimated using the EPI Suite software. This estimation suggests that photodegradation may be a significant mechanism for the breakdown of sodium isethionate in the atmosphere. Based on the model estimates, the hydroxyl radical reaction half-life was about 24 hours. With respect to stability in water, no hydrolysis information is available for sodium isethionate, however, hydrolysis is not a critical endpoint as SI is primarily eliminated via biodegradataion, as described below. The material can therefore be expected to be highly removed through wastewater treatment processes and in the environment. Data for hydrolysis or photolysis would not provide any significant additional information on the fate of the material.

Measured biodegradation data are available from five separate studies for sodium isethionate and are summarized in Table 3. These data indicate substantial microbial degradation under aerobic conditions. In the first study, conducted to GLP, sodium isethionate of 95.3% purity was tested in accordance with OECD Guideline 301A and EU Directive 92/69/EEC, C.4A. Results show that DOC elimination reached 98% and 101% in just 10 days for the two samples tested at 121 mg/L. In the second study, sodium isethionate as a 57% aqueous solution was tested using the Modified Sturm Test (OECD Guideline 301B). After 28 days the percent biodegradation was 66% and 76% (average 71%) for the two samples tested at 181.3 mg/L and 176.8 mg/L, respectively. Sodium benzoate was used as the positive control and resulted in 74% degradation, confirming the viability of the inoculum (activated sludge). Although this second study was not conducted according to GLP, it is a well conducted, reliable study that shows SI is readily biodegradable.

Table 3. Summary of Biodegradation Studies

Test Material	Value	Source	Reliability
Lutensit A-IS 95.3%	90-100% after 10 days	Taeger 2006	1
Hostapon SI 57%	71% after 28 days	Hirschen and Weber 2004	2
SI	>90% after 22 days	IUCLID 2000 (Hoechst 1986)	4
SI	63% after 15 days	IUCLID 2000 (Hoechst 1979)	4
SI	82% after 15 days	IUCLID 2000 (Hoechst 1980)	4

Three additional biodegradation studies were reported in the 2004 IUCLID data set. All three studies were conducted in accordance with OECD Guideline 302B, "Inherent Biodegradability: Modified Zahn-Wellens Test." Results showed biodegradation of >90% after 22 days, 63% after 15 days, and 82% after 15 days, respectively.

The IUCLID data set also reports BOD_5 values of 400 mg O_2/L and COD values of 570 and 600 mg/g substance. In addition, bioaccumulation was estimated using the EPI Suite software. The calculated BCF of sodium isethionate was 3.162 (log BCF = 0.500), which indicates that SI is not likely to bioaccumulate in body tissues.

Results of the environmental fate and transport studies demonstrate that sodium isethionate is readily biodegradable and has a very low affinity for bioaccumulation. Based on the availability of high quality biodegradation data and other estimated values, no further testing of environmental fate endpoints is being proposed at this time.

Ecotoxicity

Several studies are available to evaluate the aquatic toxicity of sodium isethionate (Table 4).

Well documented GLP studies are available to address the acute aquatic toxicity of sodium isethionate to the zebra fish (*Brachydanio rerio*). In the first study, zebra fish were exposed to static concentrations up to 10,000 mg/L for 96 hours in accordance with OECD Guideline 203. Sodium isethionate of 95.3% purity was used. After 96 hours, no mortality or other effects were observed at any test concentration (LC_{50} > 10,000 mg/L). In the second study, zebra fish were exposed to a limit test concentration of 100 mg/L, again according to OECD Guideline 203. Again, no mortality was observed during the 96 hour study. Some behavioral changes (hypoactivity, swimming posture, projecting opercula, irregular respiration) were observed in the first 3-6 hours of the study but disappeared after 24 hours. The 96 hour LC_{50} was greater than the limit concentration of 100 mg/L.

Table 4. Summary of Aquatic Toxicity Studies

Test Material	Value	Source	Reliability
Fish (*Brachydanio rerio*)			
Lutensit A-IS 95.3%	96-h LC_{50} >1.0 x 10^4 mg/L	Munk 1998	1
SI 97%	96-h LC_{50} >100 mg/L	Zok 1996	1
Invertebrate (*Daphnia magna*)			
Lutensit A-IS 95.3%	48-h EC_{50} >100 mg/L	Maisch 1997a	1
Hostapon SI 57%	48-h EC_{50} >1000 mg/L	Noack 2005	1
SI	48-h EC_{50} >1000 mg/L	IUCLID 2000 (Hoechst 1986)	4
Algae (*Scenedesmus subspicatus*)			
Lutensit A-IS 95.3%	72-h EC_{50} >100 mg/L	Maisch 1997b	1
Microorganisms (Bacteria)			
SI	24-h EC_{50} >2500 mg/L	IUCLID 2000 (Hoechst 1986)	4
SI	24-h SG = 1500 mg/L	IUCLID 2000 (Hoechst 1979)	4
SI	24-h SG = 800 mg/L	IUCLID 2000 (Hoechst 1980)	4

Well documented GLP studies are also available regarding the acute aquatic toxicity of sodium isethionate to *Daphnia magna*. In the first study, *Daphnia* were exposed to five concentrations ranging from 6.25 to 100 mg/L of 95.3% pure sodium isethionate for 48 hours. No immobilization or other effect was observed during the study, except for the mortality of two animals in the 25 mg/L concentration that appeared unrelated to the test material. The 48 hour EC_{50} is greater than the highest concentration tested, 100 mg/L. In the second study, *Daphnia* were exposed in a limit test to 1000 mg/L sodium isethionate in a 57% aqueous solution for 48 hours. Again, no mortality or other effects were observed during the study. The 48 hour EC_{50} is greater than the limit concentration of 1000 mg/L.

The aquatic toxicity to the green unicellular algae, *Scenedesmus subspicatus*, was evaluated in a well documented GLP study using 95.3% pure sodium isethionate. Algae were exposed to nine concentrations ranging from 0.29 to 100 mg/L for 72 hours. Cell counts were made with a Newbauer counting chamber and any inhibition on biomass and growth rate was noted. Results indicate no significant effects on either biomass or growth rate during the study. The resultant 72 hour EC_{50} was greater than the highest concentration tested of 100 mg/L.

Toxicity to aquatic anaerobic bacteria was also evaluated in three studies reported in the IUCLID 2000 data set. In the first study using the ETAD Fermentation tube method, the resultant EC_{50} value was >2500 mg/L. In the second two studies, again using the ETAD Fermentation tube method, results indicate an SG (equivalent to a lowest observable effect concentration) of 1500 and 800 mg/L, respectively.

Estimates of chronic aquatic toxicity data were made using the EPA's ECOSAR software. The calculated fish 30 day ChV (chronic value) was 4.74 x 10^7 mg/L. The calculated 16 day daphnid EC_{50} was 1.52 x 10^6 mg/L. Similarly, ECOSAR was used to estimate the 14 day LC_{50} of the terrestrial earthworm as 1.86 x 10^5 mg/L.

In summary, both high quality experimental studies and estimated data are available for the aquatic toxicity endpoints and demonstrate that sodium isethionate is not toxic to aquatic organisms. Based on the available information, which indicates low toxicity to aquatic organisms, high water solubility and ready biodegradation, plus the very low estimated log K_{ow}, no chronic aquatic toxicity would be expected. Furthermore, due to the low aquatic toxicity and likely low partitioning to soils and sediments, terrestrial toxicity is unlikely. Therefore, no further ecological toxicity studies are being proposed at this time.

Toxicity

The available data to assess the mammalian toxicity of sodium isethionate are shown in Table 5. Two well documented GLP studies are available to evaluate the acute oral toxicity of sodium isethionate to mammals. In the first study, male and female Wistar rats were given a single limit dose of 2000 mg/kg bw in an aqueous vehicle by gavage. Animals were observed for 14 days post-administration for signs of stress or toxicity and then necropsied to evaluate any internal signs. No mortality was observed during the study. No effects were observed in any of the female animals. Non-specific signs of toxicity were observed in the male animals within 1-3 hours after administration, including impaired general state, dyspnoea, staggering, and diarrhea. These animals all appeared normal within 2 days after application and remained that way. No effects on body weight gain and no abnormalities at necropsy were observed. In the second study, male and female Wistar rats were given a single oral dose of 5000 mg/kg bw in distilled water by gavage and observed for 14 days. No mortality was observed during the study with the exception of one female at the one week time period. Necropsy revealed no apparent signs of toxicity and its death did not appear to be treatment related. No other effects were observed in any of the remaining animals.

Table 5. Summary of Mammalian Toxicity Studies

Test Material	Value	Source	Reliability
Acute Oral			
Lutensit A-IS 95.3%	LD_{50} >2000 mg/kg	Kuehlem 1998a	1
SI 97%	LD_{50} >5000 mg/kg	Hofmann and Hollander 1986a	1
Skin Irritation			
Lutensit A-IS 95.3%	Not irritating	Kuehlem 1998b	1
SI 97%	Not irritating	Hofmann and Hollander 1986b	1
Eye Irritation			
Lutensit A-IS 95.3%	Not irritating	Kuehlem 1998c	1
SI 97%	Not irritating	Hofmann and Hollander 1986c	1
Genotoxicity – Ames Test			
SI 99.6%	Negative (with and without S-9) (*Salmonella typhimurium*)	Stammberger 1993	1
SI 99.6%	Negative (with and without S-9) (*Escherichia coli*)	Stammberger 1993	1

No specific data are available on acute inhalation or acute dermal toxicity. Inhalation is not expected to be a significant route of exposure. Furthermore, while no specific acute dermal toxicity data were located, data are available on dermal exposure in two GLP skin irritation studies. In the first study, the skin on the backs of healthy white rabbits was exposed to a single dose of 0.5 g sodium isethionate (95.3% purity) for four hours. The test sites were covered with a test patch held in place with a semi-occlusive dressing. After four hours the patches were removed and the areas rinsed. Barely perceptible erythema was observed in all three animals at the one hour observation time, but this had completely disappeared by 24 hours. In the second study, 0.1 mL of 500 mg sodium isethionate (≥97% purity) was applied to the intact skin on the backs of three rabbits and covered with a test patch and a semi-occlusive dressing. After four hours the patch was removed and the area rinsed. Results indicate no incidence of erythema/eschar or edema at any time during the study. Based on these two studies, sodium isethionate is not irritating to the skin.

Eye irritation was also examined in two GLP studies. In the first study, a single application of 0.1 mL (approximately 58 mg) of sodium isethionate (95.3% purity) was placed in the conjunctival sac of three rabbits. After 24 hours this was washed out and readings taken at 1, 24, 48 and 72 hours after application. No effects were observed for corneal opacity or iris. Minor chemosis was observed at the one hour period only and disappeared shortly thereafter. Minor conjunctival redness was observed at the one and 24 hour periods but not thereafter. Similarly, conjunctival discharge was observed at one hour but not thereafter. In the second study, a single application of 0.1 mL (100 mg) of sodium isethionate (≥97% purity) was placed in the conjunctival sac of one eye in each of three rabbits and washed out after 24 hours. Swelling of the lids and redness of the conjunctiva and iris were observed one hour after application. A clear discharge was also observed. These symptoms were reduced at 24 hours and disappeared by 48 hours.

Data were not available for the sensitization, repeated dose, reproductive and developmental toxicity endpoints.

Well documented GLP data are available to evaluate genotoxicity. In a bacterial reverse mutation assay (Ames test), five strains of *Salmonella typhimurium* were exposed to sodium isethionate (99.6% purity) concentrations ranging from 4 to 5000 µ/plate. Tests were conducted both with and without S-9 metabolic activation. Results demonstrated no significant increases in revertant colonies in any of the tester strains either in the presence or absence of S-9 mix. In a second study conducted with *Escherichia coli* with the same test material at the same concentrations, no significant effects were observed. These studies confirm that sodium isethionate is not mutagenic in these test systems. DEREK and TIMES structure activity software both predict that SI will be non-mutagenic and has no structural alerts for this endpoint (Unilever personal communication).

In summary, well documented studies are available for many of the toxicity endpoints. These data demonstrate that sodium isethionate is not acutely toxic, not a skin or eye irritant, and not mutagenic. Data are not available for the sensitization, repeated dose, reproductive and developmental toxicity endpoints. However, structure activity software predictions indicate that no alerts were seen for SI for skin sensitization and skin penetration is predicted as low (Unilever personal communication). Given the fact that sodium isethionate does not show any significant toxicity characteristics in the available studies, it is unclear that conducting additional long-term exposure studies would provide any new information. Furthermore, mammalian toxicity data for sodium cocoyl isethionate from repeated dose studies conducted via both oral and dermal routes show no significant systemic toxicity. These repeated dose data are relevant for read across to SI as ADME studies indicate that SCI is metabolized to SI by hydrolysis of the ester bond in SCI (see Howes 1975 in robust summary document). Therefore, in the interest of responsible animal welfare management the SESC is proposing not to conduct additional animal testing at this time.

Evaluation of Data Completeness

Substantial data are available for sodium isethionate. These data are derived from a variety of sources, including GLP laboratory studies, IUCLID-reported studies, and estimations using the EPA models EPI Suite and ECOSAR. Data for physical-chemical properties are primarily based on EPI Suite estimations. EPI Suite was also used to estimate photodegradation and fugacity-based distribution in the environment. High quality GLP studies have been provided to address the biodegradation endpoint. Similarly, high quality GLP studies are provided to meet the requirements for acute aquatic toxicity. For mammalian toxicity, high quality GLP studies are available for acute oral toxicity, as well as skin and eye irritation and mutagenicity with *Salmonella typhimurium* and *E. coli*. Data are not available to address the skin sensitization, repeated dose, reproductive and developmental toxicity endpoints. However, read across from the SCI data set could help to address some of these endpoints for SI.

SUMMARY OF SODIUM ISETHIONATE PROPERTIES

Sodium isethionate is an intermediate in the production of SCI and also may be a component in syndet bars and other cleansers and cosmetics. SI is highly soluble in water and has a very low affinity for bioaccumulation. SI is readily biodegradable, generally exhibiting 63-100% degradation in as little as 10 days. SI was found to be non toxic to aquatic organisms. No mortality or other significant effects were observed in several acute toxicity tests conducted on fish, *Daphnia*, and algal species. SI also exhibited no apparent toxicity in mammalian toxicity studies. It is not irritating to the skin or eyes of rabbits, and is not mutagenic to *Salmonella* or *E. coli* in genotoxicity studies. No data are available for the skin sensitization, repeated dose, reproductive and developmental toxicity endpoints. However, based on the lack of observed toxicity demonstrated in all of the available studies, and in the interest of responsible animal welfare management, the SESC is not proposing to conduct additional animal testing at this time.

Table 6 summarizes the availability of data and assessment plan status for sodium isethionate.

It should be noted that separate robust summary and assessment plan documents, also prepared in support of the HPV Challenge program, are available for sodium cocoyl isethionate (SCI). SI is used as an intermediate in the synthesis of SCI, and some SI is also present in the final products that use SCI as the primary ingredient. As a consequence, several of the studies summarized in the SCI robust summary document were conducted on products that contain up to 15% SI in their composition. Furthermore, several Repeat Insult Patch Tests (RIPT) have been conducted for products containing both SCI and SI and are reported in the SCI documents. Therefore, the SCI documents should be consulted for additional information relevant to the evaluation of SI.

CONCLUSIONS

Substantial data are available for sodium isethionate. These data consistently demonstrate that sodium isethionate is not toxic to aquatic or mammalian organisms. Worker exposure is adequately controlled by engineering controls and the use of personal protective equipment. Dermal exposure occurs through use of moisturizing detergent bar soaps and body washes and cosmetic use of products containing SI. However, studies confirm that SI is not irritating to the skin, and in fact is much milder to the skin than conventional soap products.

Based on the availability of data and the lack of toxicity, sodium isethionate is considered to be of low concern and no further animal testing is being proposed at this time.

Table 6. Data Availability and Status for Sodium Isethionate

	Data Available	**Data Acceptable**	**Testing Required**
Physical-Chemical Properties			
Melting Point	Y	Y	N
Boiling Point	Y	Y	N
Vapor Pressure	Y	Y	N
Octanol/Water Partition Coefficient	Y	Y	N
Water Solubility	Y	Y	N
Environmental Fate and Pathways			
Photodegradation	Y	Y	N
Stability in Water	N	-	N
Biodegradation	Y	Y	N
Bioaccumulation	Y	Y	N
Ecotoxicity			
Acute/Prolonged Toxicity to Fish	Y	Y	N
Acute Toxicity to *Daphnia*	Y	Y	N
Toxicity to Aquatic Plants (algae)	Y	Y	N
Chronic Toxicity to Fish	Y	Y	N
Chronic Toxicity to Aquatic Invertebrates	Y	Y	N
Toxicity			
Acute Oral Toxicity	Y	Y	N
Acute Inhalation Toxicity	N	-	N
Acute Dermal Toxicity	N	-	N
Skin Irritation	Y	Y	N
Eye Irritation	Y	Y	N
Skin Sensitization	N	-	N
Repeated Dose Toxicity	N	-	N
Genetic Toxicity in vitro (Bacterial test)	Y	Y	N
Genetic Toxicity in vitro (Non-bacterial test)	N	-	N
Genetic Toxicity in vivo	N	-	N
Carcinogenicity	N	-	N
Toxicity to Reproduction	N	-	N
Developmental Toxicity	N	-	N

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I U C L I D

Data Set

Existing Chemical Substance ID: Ethanesulfonic acid, 2-hydroxy-, monosodium salt (Sodium Isethionate)

Producer Related Part
Company: Keller and Heckman LLP
Creation date: 24-NOV-2006

Substance Related Part
Company: Keller and Heckman LLP
Creation date: 24-NOV-2006

Printing date: 24-NOV-2006
Revision date:
Date of last Update: 24-NOV-2006

Number of Pages: 30

Chapter (profile): Chapter: 1, 2, 3, 4, 5, 7
Reliability (profile): Reliability: without reliability, 1, 2, 3, 4
Flags (profile): Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC

1.0.1 OECD and Company Information

Name:	The Sodium Ethyl Sulfonates Coalition (SESC)
Remark:	The Coalition consists of: BASF Corporation Clariant Corporation Huntsman Petroleum Corporation Unilever Home and Personal Care

1.0.2 Location of Production Site

Remark: Not an HPV Challenge endpoint.

1.0.3 Identity of Recipients

Remark: Not an HPV Challenge endpoint.

1.1 General Substance Information

Substance type:	organic
Physical status:	solid
Test substance:	Ethanesulfonic acid, 2-hydroxy-, monosodium salt and hereafter referred to as Sodium Isethionate (CAS# 1562-00-1; EINECS# 216-343-6)

1.1.1 Spectra

Remark: Not an HPV Challenge endpoint.

1.2 Synonyms

Sodium isethionate
Ethanesulfonic acid, 2-hydroxy-, monosodium salt
2-Hydroxyethanesulfonic acid, sodium salt
Isethionic acid, sodium salt
Sodium hydroxyethylsulfonate

1.3 Impurities

Remark: <1 ppm ethylene oxide

1.4 Additives

Remark: None identified

1.5 Quantity

Quantity 10,000-50,000 tons

1.6.1 Labelling

Remark: No specific labeling required.

1.6.2 Classification

Remark: No specific classification.

1.7 Use Pattern

Remark: Primarily used in synthetic and combination detergent bar soaps. Other uses of SI include skin cleansing and personal washing agents, cosmetics, intermediates, and ingredients in shampoo and bubble baths. Most of the production of SI is used as an intermediate in the production of sodium cocoyl isethionate for use directly in personal wash products, and as such SCI is primarily regulated by the US Food and Drug Administration and are not TSCA-reportable.

1.7.1 Technology Production/Use

Remark: Not an HPV Challenge endpoint.

1.8 Occupational Exposure Limit Values

Remark: No TLV has been established

1.9 Source of Exposure

Remark: See discussion in accompanying sodium isethionate assessment plan.

1.10.1 Recommendations/Precautionary Measures

Remark: See sodium isethionate assessment plan.

1.10.2 Emergency Measures

Remark: See sodium isethionate assessment plan.

1.11 Packaging

Remark: Bulk, small and large packaging

1.12 Possib. of Rendering Subst. Harmless

Remark: Not applicable

1.13 Statements Concerning Waste

Remark: See sodium isethionate assessment plan.

1.14.1 Water Pollution

Remark: Not a significant source of water pollution.

1.14.2 Major Accident Hazards

Remark: None

1.14.3 Air Pollution

Remark: Not a significant source of air pollution.

1.15 Additional Remarks

Remark: None

1.16 Last Literature Search

Date of Search: 28-FEB-2006

1.17 Reviews

Remark: None

1.18 Listings e.g. Chemical Inventories

Remark: TSCA inventory (USA)
Domestic Substances List (DSL) - Canada
EINECS (Europe)

2.1 Melting Point

(a)
Value: 193-196°C
GLP: Not reported
Remark: Reported in IUCLID citing Hoechst AG Safety Data Sheets and Product Information Sheets (dated 1993, 1994, 1995)
Test substance: Sodium 2-hydroxyethane sulphonate (1562-00-1)
Source: IUCLID Data Set. CAS No. 1562-00-1. Sodium 2-hydroxyethane sulphonate. February 18, 2000. Year 2000 CD-ROM Edition.
Reliability: (4) Not assignable. As reported in IUCLID. Original study report not available.

(b)
Value: 214.41°C
GLP: No
Remark: Calculated using the Mean or Weighted MP method in MPBPWIN v1.41
Test substance: Sodium isethionate; Molecular weight 148.11
Source: EPI Suite v3.12.
Reliability: (2) Valid with restrictions. Standard EPA Estimation software.

(c)
Value: 191-194°C
GLP: Not reported
Remark: Cited in ChemFinder database
Source: Chemfinder.com Database & Internet Searching
Test substance: Ethanesulfonic acid, 2-hydroxy-, monosodium salt (1562-00-1)
Reliability: (4) Not assignable. Secondary source of data.

2.2 Boiling Point

(a)
Value: >230°C
GLP: Not reported
Remark: Decomposes. Reported in IUCLID citing Hoechst AG Safety Data Sheets and Product Information Sheets (dated 1993, 1995). Method reported as DTA, with a heating rate of 10°K/min.
Test substance: Sodium 2-hydroxyethane sulphonate (1562-00-1)
Source: IUCLID Data Set. CAS No. 1562-00-1. Sodium 2-hydroxyethane sulphonate. February 18, 2000. Year 2000 CD-ROM Edition.
Reliability: (4) Not assignable. As reported in IUCLID. Original study report not available.

(b)
Value: 503.88°C
GLP: No
Remark: Calculated using the Adapted Stein & Brown method in MPBPWIN v1.41
Test substance: Sodium isethionate; Molecular weight 148.11
Source: EPI Suite v3.12.
Reliability: (2) Valid with restrictions. Standard EPA Estimation software.

2.3 Density

Value: 800-1000 kg/m^3 (bulk density)
GLP: Not reported
Remark: Reported in IUCLID citing Hoechst AG Safety Data Sheets and Product Information Sheets (dated 1993, 1994, 1995)
Test substance: Sodium 2-hydroxyethane sulphonate (1562-00-1)
Source: IUCLID Data Set. CAS No. 1562-00-1. Sodium 2-hydroxyethane sulphonate. February 18, 2000. Year 2000 CD-ROM Edition.
Reliability: (4) Not assignable. As reported in IUCLID. Original study report not available.

2.3.1 Granulometry

Remark: Not an HPV Challenge endpoint.

2.4 Vapor Pressure

Value: 1.37 x 10^{-12} mm Hg at 25°C
GLP: No
Remark: Calculated using the Modified Grain method in MPBPWIN v1.41
Test substance: Sodium isethionate; Molecular weight 148.11
Source: EPI Suite v3.12.
Reliability: (2) Valid with restrictions. Standard EPA Estimation software.

2.5 Partition Coefficient

Value: Log K_{ow} = -5.50 at 25°C
GLP: No
Remark: Calculated using KOWWIN v.1.67
Test substance: Sodium isethionate; Molecular weight 148.11
Source: EPI Suite v3.12.
Reliability: (2) Valid with restrictions. Standard EPA Estimation software.

2.6.1 Water Solubility

(a)
Value: 1 x 10^6 mg/L at 25°C
GLP: No
Remark: Calculated using WSKOW v1.41 and the estimated log K_{ow} of -5.50. No melting point equation used.
Test substance: Sodium isethionate; Molecular weight 148.11
Source: EPI Suite v3.12.
Reliability: (2) Valid with restrictions. Standard EPA Estimation software.

(b)
Value: 650 g/L at 20°C
GLP: Not reported
pH: Reported as 11-11.5 at 100 g/L and 8-11 at 10 volume percent, both at 20°C.
Remark: Reported in IUCLID citing Hoechst AG Safety Data Sheets and Product Information Sheets (dated 1993, 1994, 1995)
Test substance: Sodium 2-hydroxyethane sulphonate (1562-00-1)
Source: IUCLID Data Set. CAS No. 1562-00-1. Sodium 2-hydroxyethane sulphonate. February 18, 2000. Year 2000 CD-ROM Edition.
Reliability: (4) Not assignable. As reported in IUCLID. Original study report not available.

2.6.2 Surface Tension

Remark: Not an HPV Challenge endpoint.

2.7 Flash Point

Value: >242°F (>116.6°C)
>200°F (>93.3°C)
Remark: Data from MSDS sheets for 57% and 50-65% aqueous solutions, resp.

2.8 Auto Flammability

Value:
Remark: Not flammable.

2.9 Flammability

Result:
Remark: Not flammable.

2.10 Explosive Properties

Result:
Remark: Not explosive.

2.11 Oxidizing Properties

Result:
Remark: Not an oxidizer.

2.12 Additional Remarks

Memo: None

3.1.1 Photodegradation

Type: atmospheric oxidation
INDIRECT PHOTOLYSIS
Sensitizer: OH
Conc. of sens.: 1.5×10^6 molecule/cm^3
Rate constant: 5.3097×10^{-12} cm^3/(molecule * sec)
Degradation: = 50 % after 24.2 hours
Method: Calculated: Hydroxy Radical Reaction using AOPWIN, V1.91 at 25°C
Year: 2006 **GLP:** no
Test substance: Sodium isethionate; molecular weight 148.11
Source: EPI Suite v3.12
Reliability: (2) valid with restrictions. Standard EPA Estimation software.

3.1.2 Stability in Water

Remark: No data available

3.1.3 Stability in Soil

Remark: Not an HPV Challenge endpoint.

3.2 Monitoring Data (Environment)

Remark: No data available

3.3.1 Transport between Environmental Compartments

Remark: Not an HPV Challenge endpoint.

3.3.2 Distribution

Method: Calculation using Fugacity Level III in EPI Suite
Remark: Mass Distribution by Environmental Compartment

Air:	0.173%
Water:	34.7%
Soil:	65.1%
Sediment:	0.06%

GLP: No
Test substance: Sodium isethionate; Molecular weight 148.11
Source: EPI Suite v3.12.
Reliability: (2) Valid with restrictions. Standard EPA Estimation software.

3.4 Mode of Degradation in Actual Use

Memo: Sodium isethionate is readily degraded by biological means.

3.5 Biodegradation

(a)

Type: aerobic
Inoculum: activated sludge
Concentration: 121 mg/l (corresponding to 20 mg/L DOC)
Contact time: 10 day
Degradation: 90-100 % after 10 days
Method: In accordance with OECD Guideline 301A and EU Directive 92/69/EEC, C.4A. The DOC decrease test is a static test to determine the complete aerobic biodegradability of a test substance in water. The test substance, a defined organic medium and an inoculum that has not been preadapted are incubated and aerated at room temperature up to 28 days. Samples are taken at regular intervals and measured for dissolved organic carbon (DOC). Negative and positive control tests are also conducted. Inoculum inhibition from the test substance and study of abiotic elimination and absorption to the inoculum are also investigated. The activated sludge for the study came from laboratory wastewater treatment plants that are operated with municipal and synthetic wastewater. The positive control used was aniline at a concentration of 20 mg/L. The test substance concentration used was 121 mg/L, which corresponds to 20 mg/L DOC.
Year Conducted: 1996 **GLP:** yes
Test substance: Lutensit A-IS Pulver (Sodium 2-Hydroxyethylsulfonate) [Sodium isethionate]; CAS No. 1562-00-1; Barrel No. 60; white powder; purity 95.3%; miscible up to 10 g/L
Result: Lutensit A-IS (sodium isethionate) is readily biodegradable. As shown in the table below, the test substance reached the level of 10% degradation within 5 days and then 100% by day 10.

Test substance	**Percent DOC Elimination**						
	Day 0	**Day 1**	**Day 3**	**Day 5**	**Day 7**	**Day 9**	**Day 10**
Aniline (20 mg/L) (positive control)	0	6	-2	91	95	94	99
Lutensit A-IS (121 mg/L) (Sample 1)	0	5	-7	24	96	96	98
Lutensit A-IS (121 mg/L) (Sample 2)	0	7	-7	22	97	97	101

Remarks: The study passed all the relevant validity criteria.
Source: Taeger, Dr. 2006. Study of the biodegradability of Lutensit A-IS Pulver in the DOC decrease (die away) test. BASF Corporation, Laboratory Project No.96/0154/21/1 (English translation of German report, original report date 1996).
Reliability: (1) valid without restriction. Well documented GLP study.

(b)
Type: aerobic
Inoculum: activated sludge
Concentration: 179.1 mg/l
Contact time: 28 day
Degradation: = 71 % after 28 days
Method: Modified Sturm Test according to OECD Guideline 301B. Test vessels were 5-L brown glass bottles fitted with an aeration tube and outlet, and each containing 3 liters of mineral medium. There were two vessels for the inoculum control, two vessels for the test substance at a concentration averaging 179.1 mg/L (181.3 and 176.8 mg/L), and one vessel for the reference substance (sodium benzoate at 20 mg/L). The vessels were inoculated with activated sludge from a sewage treatment plant in Frankfurt, Germany. The degradation was followed by CO_2 analysis at frequent intervals over a 28-day period at 22 ± 2°C in diffuse light. The produced CO_2 was trapped in barium hydroxide and expressed as a percentage of the theoretical CO_2 ($ThCO_2$). A test substance is considered to have passed the test if 60% of the $ThCO_2$ production is achieved within 10 days of reaching 10% biodegradation.
Year Conducted: 2004 **GLP:** no
Test substance: Hostapon SI 57% (2-Hydroxyethansulfonic acid, sodium [Sodium isethionate] in a 57% watery solution; CAS No. 1562-00-1; Batch No. ESDB006354; clear liquid)
Result: Hostapon SI 57% is readily biodegradable. As shown in the table below,

the test substance reached the level of 10% degradation after 10 days and achieved the 60% level after 12.5 days.

Test substance	**Percent Biodegradation**							
	Day 2	**Day 5**	**Day 7**	**Day 9**	**Day 12**	**Day 16**	**Day 21**	**Day 28**
Sodium benzoate (20 mg/L)(positive control)	25	44	60	67	71	72	73	74
Hostapon SI #1 (181.3 mg/L)	0	7	32	46	57	61	64	66
Hostapon SI #2 (176.8 mg/L)	1	14	37	56	65	69	73	76

Remarks: The study passed all the relevant validity criteria.
Source: Hirschen, D.M, and Weber, K. 2004. Hostapon SI 57%: Ready Biodegradability in the OECD 301B "CO_2 Evolution Test (Modified Sturm Test)." Clariant GmbH, Division Functional Chemicals, Frankfurt. Report No. I942.
Reliability: (2) valid with restrictions. The study was performed according to GLP principles and the OECD Guideline 301B but was did not include the GLP statement.

(c)

Type: aerobic
Inoculum: activated sludge, industrial, non-adapted
Concentration: not reported
Contact time: at least 22 days
Degradation: >90% after 22 days
Kinetic: 3 hours = ca. 10%
5 days = 20%
10 days = 45%
15 days = 75%
Results: Based on the degradation reported, the test substance appears to be readily biodegradable under the test conditions.
Method: OECD Guideline 302B "Inherent biodegradability: Modified Zahn-Wellens Test."
Year Conducted: 1986 **GLP:** no
Test substance: Sodium 2-hydroxyethane sulphonate (1562-00-1)
Remarks: Reported in IUCLID Data Set citing Hoechst AG (1986) Unpublished report No. OEK W85-439 dated 20.01.1986.
Source: IUCLID Data Set. CAS No. 1562-00-1. Sodium 2-hydroxyethane sulphonate. February 18, 2000. Year 2000 CD-ROM Edition.
Reliability: (4) Not assignable. As reported in IUCLID. Original study report not available.

(d)

Type: aerobic
Inoculum: activated sludge, industrial, non-adapted
Concentration: not reported
Contact time: at least 15 days
Degradation: 63% after 15 days
Kinetic: 5 days = 20%
10 days = 56%
Results: Based on the degradation reported, the test substance appears to be readily biodegradable under the test conditions.
Method: OECD Guideline 302B "Inherent biodegradability: Modified Zahn-Wellens Test."
Year Conducted: 1979 **GLP:** no
Test substance: Sodium 2-hydroxyethane sulphonate (1562-00-1)
Remarks: Reported in IUCLID Data Set citing Hoechst AG (1979) Unpublished report dated 26.09.1979.
Source: IUCLID Data Set. CAS No. 1562-00-1. Sodium 2-hydroxyethane sulphonate. February 18, 2000. Year 2000 CD-ROM Edition.
Reliability: (4) Not assignable. As reported in IUCLID. Original study report not available.

(e)

Type: aerobic
Inoculum: activated sludge, industrial, non-adapted
Concentration: not reported
Contact time: at least 15 days
Degradation: 82% after 15 days
Kinetic: 5 days = 68%
10 days = 74%
Results: Based on the degradation reported, the test substance appears to be readily biodegradable under the test conditions.
Method: OECD Guideline 302B "Inherent biodegradability: Modified Zahn-Wellens Test."
Year Conducted: 1980 **GLP:** no
Test substance: Sodium 2-hydroxyethane sulphonate (1562-00-1)
Remarks: Reported in IUCLID Data Set citing Hoechst AG (1980) Unpublished

report dated 12.06.1980.

Source: IUCLID Data Set. CAS No. 1562-00-1. Sodium 2-hydroxyethane sulphonate. February 18, 2000. Year 2000 CD-ROM Edition.

Reliability: (4) Not assignable. As reported in IUCLID. Original study report not available.

3.6 BOD5, COD or BOD5/COD Ratio

(a)

Method: Not reported

Year: 1980

GLP: no

BOD5: 400 mg O_2/L

COD: 570 mg/g substance

Remarks: Reported in IUCLID Data Set citing Hoechst AG (1980) Unpublished report dated 12.06.1980.

Source: IUCLID Data Set. CAS No. 1562-00-1. Sodium 2-hydroxyethane sulphonate. February 18, 2000. Year 2000 CD-ROM Edition.

Reliability: (4) Not assignable. As reported in IUCLID. Original study report not available.

(b)

Method: Not reported

Year: 1986

GLP: no

COD: 600 mg/g substance

Remarks: Reported in IUCLID Data Set citing Hoechst AG (1986) Unpublished report No. OEK W85-439 dated 20.01.1986.

Source: IUCLID Data Set. CAS No. 1562-00-1. Sodium 2-hydroxyethane sulphonate. February 18, 2000. Year 2000 CD-ROM Edition.

Reliability: (4) Not assignable. As reported in IUCLID. Original study report not available.

3.7 Bioaccumulation

BCF: 3.162 (log BCF = 0.500)

Method: Calculation using BCFWIN v2.15 based on estimated log Kow = -3.36

Year: 2006 **GLP:** no

Test substance: Sodium isethionate, molecular weight = 148.11

Remark: A BCF of 3.162 indicates a very low affinity for uptake.

Source: EPI Suite v3.12.

Reliability: (2) valid with restrictions. Standard EPA Estimation software.

3.8 Additional Remarks

Memo: None

AQUATIC ORGANISMS

4.1 Acute/Prolonged Toxicity to Fish

(a)

Type: Static
Species: *Brachydanio rerio* (Zebra Fish, FW)
Endpoint: Mortality
Exposure period: 96 hours
Unit: mg/L **Analytical monitoring:** yes
LC_{50}: $>1.0 \times 10^{4}$
Method: The study was conducted in accordance with OECD Guideline 203. Aquaria containing 10 liters were loaded with 10 fish each (mean weight 0.33 g; mean length 3.53 cm). The test substance was added directly to the test chambers to achieve test concentrations of 464, 1000, 2150, 4640 and 10000 mg/L plus a non-treated control. Fish were placed into the chambers within approximately 25 minutes of adding the test substance. Test chambers were not replenished during the study (i.e., a static test). The dilution water was municipal tap water from the city of Frankenthal with a hardness of about 250 mg/L as $CaCO_3$ and a pH of 8.0-8.6. The study was conducted in a temperature controlled room at 22°C and a 16:8 hour light:dark photoperiod. Test concentrations were verified by ion chromatography and conductivity detection. Fish were not fed during the 96 hour exposure period.
Year Conducted: 1998 **GLP:** yes
Test substance: Lutensit A-IS Pulver (Sodium 2-Hydroxyethylsulfonate) [Sodium isethionate]; CAS No. 1562-00-1; Barrel No. 60; white powder; purity 95.3%; miscible up to 10 g/L
Remark: No mortality or other effects were observed during the study in any test concentration. The LC50, and no effect concentrations are both greater than the highest concentration tested (10,000 mg/L). Dissolved oxygen ranged between 8.3-9.0 mg/L; pH between 8.1-8.5; temperature remained steady at 22°C. The measured concentrations ranged between 90.5% and 99.4% of nominal, therefore the results are reported as nominal concentration.
Source: Munk, R. 1998. Lutensit A-IS Pulver: Acute Toxicity Study on the Zebra Fish (*Brachydanio rerio* HAM. And BUCH.) in a Static System (96 hours). BASF Corporation, Laboratory Project Number 17F0094/965020 (English translation of German report).
Reliability: (1) Valid without restriction. Well documented GLP study.

(b)

Type: Static
Species: *Brachydanio rerio* (Zebra Fish, FW)
Endpoint: Mortality
Exposure period: 96 hours
Unit: mg/L **Analytical monitoring:** yes
LC_{50}: >100 mg/L (limit test)
Method: The study was conducted in accordance with OECD Guideline 203 and EU Guideline 92/69/EWG, Part C.1. One replicate aquarium containing 10 liters was loaded with 7 fish (mean length 3.0 cm). The limit test concentration was 100 mg/L using a reconstituted dilution water. A similar untreated control aquarium was also prepared. Test chambers were not replenished during the study. The study was conducted in a temperature controlled room at 22±1°C and a 16:8 hour light:dark photoperiod. Test concentrations were verified by HPLC and UV detection. Fish were not fed during the 96 hour exposure period. Fish were observed at 3, 6, 24, 48, 72 and 96

hours for lethality and visible changes in appearance and behavior. Water parameters were measured before study initiation and after 0, 24, 48, 72 and 96 hours.

Year Conducted: 1996 **GLP:** yes

Test substance: Sodium 2-hydroxyethane sulfonic acid (sodium isethionate, 1562-00-1); minimum purity 97%.

Remark: No mortality was observed during the study in the control or test concentration. Some behavioral changes (hypoactivity, swimming posture, projecting opercula, irregular respiration) were seen in the first 3-6 hours of the study but disappeared after 24 hours. The LC_{50} is greater than the limit concentration of 100 mg/L. Dissolved oxygen ranged between 7.8-10.1 mg/L; pH between 7.6-7.9; temperature between 21.2-21.9°C. The measured concentrations were 102.3% of nominal, therefore the results are reported as nominal concentration.

Source: Zok, S. 1996. Ethansalz 97/100: 96-hour acute toxicity study in Zebra Fish (*Brachydanio rerio*). Hoechst Corporation, Report No. 96.0895

Reliability: (1) Valid without restriction. Well documented GLP study.

4.2 Acute Toxicity to Aquatic Invertebrates

(a)

Type: Static

Species: *Daphnia magna* (Crustacea)

Endpoint: immobility

Exposure period: 48 hours

Unit: mg/L **Analytical monitoring:** yes

EC_{50}: >100 (highest concentration tested)

Method: Conducted in accordance with EEC Directive 79/831/EEC, Annex V, Part C2. Five less than 24 hour old daphnids were placed each into 20 mL flat bottom glass test tubes with 10 mL of test solution or control. Four replicates were established for each of five concentrations (6.25, 12.5, 25, 50, and 100 mg/L) plus controls. All test chambers were maintained at 20±2°C under artificial light (5-6 $\mu E/(m^2 \cdot s)$) using a 16:8 hour light:dark photoperiod. Animals were checked at 0, 3, 6, 24, and 48 hours for immobilization. Concentrations were analytically verified at 0 and 48 hours using ion chromatography with conductivity detection.

Year Conducted: 1996 **GLP:** yes

Test substance: Lutensit A-IS Pulver (Sodium 2-Hydroxyethylsulfonate) [Sodium isethionate]; CAS No. 1562-00-1; Barrel No. 60; white powder; purity 95.3%; miscible up to 10 g/L

Results: No immobilizaton or other effect was observed in the control or any test concentration during the study, with the exception of the mortality of two animals in the 25 mg/L concentration. All other animals in all concentrations appeared healthy. Water quality parameters ranged from 7.9-8.1 for pH, 8.2-8.6 mg/L for dissolved oxygen content, and 18.9-20.5°C for temperature.

Remarks: Recovery rates of the test concentrations were within 100.8 to 104% of nominal, therefore nominal concentrations are reported.

Source: Maisch, Dr. 1997. Determination of the acute toxicity of Lutensit A-IS Pulver to the water flea *Daphnia magna* STRAUS. BASF Corporation, Project No. 96/0154/50/1. (English translation of German report)

Reliability: (1) valid without restriction

(b)

Type:	Static
Species:	*Daphnia magna* (Crustacea)
Endpoint:	immobility
Exposure period:	48 hours
Unit:	mg/L **Analytical monitoring:** yes
EC_{50}:	>1000
Method:	OECD Guideline 202 (2004); EC Directive 92/69/EC method C.2 (1992). Based on the results of a preliminary range finding test in which no mortality was observed, the definitive test was performed as a limit test at 1000 mg/L under static conditions for 48 hours. Twenty organisms (2-24 hrs old) were divided between 4 glass beakers (5 organisms per beaker) holding 20 mL each of the test solution or control. Elendt M4 culture medium was used, modified to a total hardness of 160 to 180 mg/ $CaCO_3$/L. Daphnids were not fed during the study. Test temperature was 18-22°C under diffuse light and a 16/8 light/dark photoperiod. Daphnids were checked at 24 and 48 hours for immobility. The limit concentration and control solutions were analytically verified with LC-MS/MS after 0 and 48 hours. Results are given as nominal concentrations. A parallel reference test using potassium dichromate was also tested using five concentrations and similar test conditions.
Year Conducted:	2005 **GLP:** yes
Test substance:	Hostapon SI 57% (2-Hydroxyethansulfonic acid, sodium [Sodium isethionate] in a 57% watery solution; CAS No. 1562-00-1; Batch No. ESDB011649; clear colorless liquid)
Results:	No immobilizaton or other effects was observed in the control or the limit concentration of 1000 mg/L at either 24 or 48 hours. All animals appeared healthy throughout the study.
Remarks:	The test material was clearly dissolved in the limit concentration throughout the duration of the study. Water quality parameters were maintained within acceptable ranges: temperature range 19-21°C, pH 7.60-7.96, dissolved oxygen 7.77-8.60 mg/L). Results of the reference study with potassium dichromate (EC_{50} = 1.84 mg/L) fell within the prescribed concentration range of 1.0-2.5 mg/L. Recovery rates of the test concentrations were >80%, therefore nominal concentrations are reported.
Source:	Noack, M. 2005. Hostapon SI 57%: Acute Immobilisation Test (Static, 48 h) to *Daphnia magna* STRAUS, Limit-Test. Dr. U. Noack Laboratorien, Study No. DA199811. Sponsored by Clariant GmbH.
Reliability:	(1) valid without restriction

(c)

Type:	Static
Species:	*Daphnia magna* (Crustacea)
Endpoint:	immobility
Exposure period:	48 hours
Unit:	mg/L **Analytical monitoring:** no
EC_{50}:	>1000
Method:	DIN 38412, Part II. No further details provided.
Year Conducted:	1986 **GLP:** no
Test substance:	Sodium 2-hydroxyethane sulphonate (1562-00-1)
Remarks:	Reported in IUCLID Data Set citing Hoechst AG (1986) Unpublished report No. OEK W85-439 dated 07.07.1986. Results for 24 and 48 hours were the same, with no effect noted at the apparent limit concentration.
Source:	IUCLID Data Set. CAS No. 1562-00-1. Sodium 2-hydroxyethane sulphonate. February 18, 2000. Year 2000 CD-ROM Edition.
Reliability:	(4) Not assignable. As reported in IUCLID. Original study report not available.

4.3 Toxicity to Aquatic Plants e.g. Algae

(a)

Type:	Static
Species:	*Scenedesumus subspicatus* (green alga)
Endpoint:	inhibition of growth rate and biomass
Exposure period:	72 hours
Unit:	mg/L **Analytical monitoring:** yes
EC_{50}:	>100 (highest concentration tested)
Method:	Conducted in accordance with EEC Directive 79/831/EEC, Annex V, Part C. The test strain of S. subpicatus is obtained at regular intervals from SAG (Collection of algal cultures in Göttingen) and kept in liquid culture in the laboratory. Test vessels were 250 mL Erlenmeyer flasks plugged with gas permeable silicone sponge caps, each containing a test volume of 100 mL. Three replicates were established for each of 9 test concentrations (0.39, 0.78, 1.56, 3.13, 6.25, 12.5, 25, 50, and 100 mg/L) plus controls. All test chambers were maintained at 23±2°C under artificial light (about 120 µE/(m^2·s) in the range of 400 to 700 nm) using a 16:8 hour light:dark photoperiod. Fluorescence at 435 nm was measured at 0, 24, 48 and 72 hours in an EOS Filterfluorometer FL2. Cell counts were made after 72 hours using a Neubauer counting chamber in replicate 1 of the inoculated control. The inoculation density was 1 x 10^4 cells/mL. The mean fluorescence was used to calculate the biomass growth and growth rate. Concentrations were analytically verified at 0 and 72 hours using ion chromatography with conductivity detection.
Year Conducted:	1996 **GLP:** yes
Test substance:	Lutensit A-IS Pulver (Sodium 2-Hydroxyethylsulfonate) [Sodium isethionate]; CAS No. 1562-00-1; Barrel No. 60; white powder; purity 95.3%; miscible up to 10 g/L
Results:	No significant effects on biomass or growth rate were observed in any test concentration during the study. The table below shows the cell density as measured by Chlorophyll-a fluorescence:

Concentration (mg/L)	0 h	24 h	48 h	72 h	Cell density after 72 h (% of control)
0 (control)	44	174	810	2924	100
100	44	167	784	2910	100
50	44	172	787	3054	104
25	44	172	825	3012	103
12.5	44	170	795	2740	94
6.25	44	171	818	2652	91
3.13	44	168	809	2678	92
1.56	42	163	839	2540	87
0.78	42	171	817	2853	98
0.39	43	172	835	2873	98

The inhibition of algal growth rates after 72 hours are shown below:

Concentration (mg/L)	**Biomass**		**Growth Rate**	
	Absolute	**Inhibition (% of control)**	**Absolute**	**Inhibition (% of control)**
0 (control)	2336	0	0.058	0
100	2296	1.7	0.058	0.1
50	2376	-1.7	0.059	-1
25	2393	-2.4	0.059	-0.7
12.5	2225	4.8	0.057	1.5
6.25	2205	5.6	0.057	2.3
3.13	2206	5.6	0.057	2.1
1.56	2167	7.2	0.057	2.2
0.78	2310	1.1	0.059	-0.5
0.39	2336	0	0.058	-0.1

Remarks: Water quality parameters were within normal acceptable levels throughout the study. Recovery rates of the test concentrations ranged from 97.8-97.9% of nominal, therefore nominal concentrations are reported.
Source: Maisch, Dr. 1997. Determination of the inhibitory effect of Lutensit A-IS Pulver on cell division of the green alga *Scenedesmus subspicatus*. BASF Corporation, Project No. 96/0154/60/1. (English translation of German report)
Reliability: (1) valid without restriction

4.4 Toxicity to Microorganisms e.g. Bacteria

(a)
Type: aquatic
Species: anaerobic bacteria from a domestic water treatment plant
Exposure period: 24 hours
Unit: mg/L **Analytical monitoring:** no
EC_0: 625
EC_{50}: >2500
Method: ETAD Fermentation tube method "Determination of damage to Effluent bacteria by the Fermentation Tube Method."
Year Conducted: 1986 **GLP:** no
Test substance: Sodium 2-hydroxyethane sulphonate (1562-00-1)
Remarks: Reported in IUCLID Data Set citing Hoechst AG (1986) Unpublished report No. OEK W85-439 dated 20.01.1986.
Source: IUCLID Data Set. CAS No. 1562-00-1. Sodium 2-hydroxyethane sulphonate. February 18, 2000. Year 2000 CD-ROM Edition.
Reliability: (4) Not assignable. As reported in IUCLID. Original study report not available.

(b)
Type: aquatic
Species: anaerobic bacteria from a domestic water treatment plant
Exposure period: 24 hours
Unit: mg/L **Analytical monitoring:** no
SG: 1500
Method: ETAD Fermentation tube method "Determination of damage to Effluent bacteria by the Fermentation Tube Method."
Year Conducted: 1979 **GLP:** no

Test substance: Sodium 2-hydroxyethane sulphonate (1562-00-1)
Remarks: SG is equivalent to a lowest observable effect concentration (LOEC). Data as reported in IUCLID Data Set citing Hoechst AG (1979) Unpublished report dated 26.09.1979.
Source: IUCLID Data Set. CAS No. 1562-00-1. Sodium 2-hydroxyethane sulphonate. February 18, 2000. Year 2000 CD-ROM Edition.
Reliability: (4) Not assignable. As reported in IUCLID. Original study report not available.

(c)
Type: aquatic
Species: anaerobic bacteria from a domestic water treatment plant
Exposure period: 24 hours
Unit: mg/L **Analytical monitoring:** no
SG: 800
Method: ETAD Fermentation tube method "Determination of damage to Effluent bacteria by the Fermentation Tube Method."
Year Conducted: 1980 **GLP:** no
Test substance: Sodium 2-hydroxyethane sulphonate (1562-00-1)
Remarks: SG is equivalent to a lowest observable effect concentration (LOEC). Data as reported in IUCLID Data Set citing Hoechst AG (1980) Unpublished report dated 12.06.1980.
Source: IUCLID Data Set. CAS No. 1562-00-1. Sodium 2-hydroxyethane sulphonate. February 18, 2000. Year 2000 CD-ROM Edition.
Reliability: (4) Not assignable. As reported in IUCLID. Original study report not available.

4.5 Chronic Toxicity to Aquatic Organisms

4.5.1 Chronic Toxicity to Fish

Type: Estimation by ECOSAR
Species: Fish
Endpoint: Mortality
Exposure period: 30 day
Unit: mg/L **Analytical monitoring:** no
ChV: 4.74×10^{7}
Method: Calculated based on Neutral Organics class
Year Conducted: 2006 **GLP:** no
Test substance: Sodium isethionate (1562-00-1); SMILES entry: [Na]OS(=O)(=O)CCO
Remark: Predicted chronic value (ChV) using estimated log Kow of -5.50 and calculated water solubility of 2.942×10^{10} mg/L.
Source: ECOSAR v.0.99g
Reliability: (2) Valid with restrictions. Standard EPA Estimation software.

4.5.2 Chronic Toxicity to Aquatic Invertebrates

Type: Estimation by ECOSAR
Species: Daphnid
Endpoint: Mortality
Exposure period: 16 day
Unit: mg/L **Analytical monitoring:** no
EC_{50}: 1.52×10^{6}
Method: Calculated based on Neutral Organics class
Year Conducted: 2006 **GLP:** no
Test substance: Sodium isethionate (1562-00-1); SMILES entry: [Na]OS(=O)(=O)CCO

Remark: Predicted EC_{50} value using estimated log Kow of -5.50 and calculated water solubility of 2.942×10^{10} mg/L.
Source: ECOSAR v.0.99g
Reliability: (2) Valid with restrictions. Standard EPA Estimation software.

TERRESTRIAL ORGANISMS

4.6.1 Toxicity to Soil Dwelling Organisms

Type: Estimation by ECOSAR
Species: Earthworm
Endpoint: Mortality
Exposure period: 14 day
Unit: mg/L **Analytical monitoring:** no
LC_{50}: 1.86×10^5
Method: Calculated based on Neutral Organics class
Year Conducted: 2006 **GLP:** no
Test substance: Sodium isethionate (1562-00-1); SMILES entry: [Na]OS(=O)(=O)CCO
Remark: Predicted LC_{50} value using estimated log Kow of -5.50 and calculated water solubility of 2.942×10^{10} mg/L.
Source: ECOSAR v.0.99g
Reliability: (2) Valid with restrictions. Standard EPA Estimation software.

4.6.2 Toxicity to Terrestrial Plants

Remark: Not an HPV Challenge endpoint.

4.6.3 Toxicity to other Non-Mamm. Terrestrial Species

Remark: Not an HPV Challenge endpoint.

4.7 Biological Effects Monitoring

Memo: Not an HPV Challenge endpoint.

4.8 Biotransformation and Kinetics

Remark: Not an HPV Challenge endpoint.

4.9 Additional Remarks

Memo: None

5.1 Acute Toxicity

5.1.1 Acute Oral Toxicity

(a)

Type: LD_{50}
Species: rat (Wistar)
Sex: male/female
Number of Animals: 6 (3 male/3 female)
Vehicle: Aqua Bidest
Value: > 2000 mg/kg bw
Method: In accordance with EEC Directive 92/69, Publication L 383A, B.1, as modified for the Acute Toxic Class Method. This was a limit test with one dose (2000 mg/kg bw). Young adult rats (150-300 g) were individually identified using cage cards and group identified using tail markings. Three male and three female animals were given a single oral administration (10 mL/kg) by gavage of the test substance in an Aqua Bidest vehicle. Animals were housed in fully air-conditioned rooms at a temperature of 22±2°C and relative humidity of 30-70% and under a 12 hour light/dark photoperiod. Each animal was housed individually in stainless steel wire cages and provided tap water and food *ad libitum*. Following the single administration, the animals were observed for 14 days for signs of stress or toxicity. All animals were necropsied on the last day of the observation period.
Year conducted: 1996 **GLP:** yes
Test substance: Lutensit A-IS Pulver (Sodium 2-Hydroxyethylsulfonate) [Sodium isethionate]; CAS No. 1562-00-1; Barrel No. 60; white powder; purity 95.3%; miscible up to 10 g/L
Results: No mortality was observed during the study period. No effects were observed in any of the female animals. Non-specific signs of toxicity observed in the male animals within 1-3 hours after administration included impaired general state, dyspnoea, staggering, and diarrhea. These animals all appeared normal within 2 days after application. No effects on body weight gain were observed. No abnormalities were observed at necropsy.
Remarks: The stability of the test substance over the duration of the test was confirmed by analysis. Results are reported as nominal dose.
Source: Kuehlem, Dr. 1998. Study on the Acute Oral Toxicity of Lutensit A-IS Pulver in Rats. BASF Corporation, Laboratory Project No. 10A0094/961030. (English translation of German report)
Reliability: (1) Valid without restriction. Well documented GLP study.

(b)

Type: LD_{50}
Species: rat (Wistar)
Sex: male/female
Number of Animals: 10 (5 male, 5 female)
Vehicle: distilled water
Value: > 5000 mg/kg bw
Method: OECD Guideline 401 "Acute Oral Toxicity." Based on the results of preliminary rangefinding studies, the study was run as a limit test with one dose (5000 mg/kg bw). Young adult rats (167-181 g) were individually identified and housed in groups of five per cage. Five male and five female animals were given a single oral administration (10 mL/kg) by gavage of the test substance in distilled water. Animals were housed in fully air-conditioned

rooms at a temperature of 22±3°C and relative humidity of 50±20% and under a 12 hour light/dark photoperiod. Animals were provided tap water and food *ad libitum*. Following the single administration, the animals were observed for 14 days for signs of stress or toxicity. All animals were sacrificed and necropsied on the last day of the observation period.

Year conducted: 1986 **GLP:** yes

Test substance: Sodium 2-hydroxyethane sulfonic acid (sodium isethionate, 1562-00-1); minimum purity 97%.

Results: No mortality was observed during the study period with the exception of one female at the one week time period. Necropsy revealed no apparent signs of toxicity in the deceased animal and it did not appear to be treatment related. No other effects were observed in any of the remaining male or female animals. No effects on body weight gain were observed. No abnormalities were observed at necropsy.

Remarks: The single mortality was not treatment related. The LD50 is greater than the limit dose of 5000 mg/kg bw.

Source: Hofmann, Dr. and Hollander, Dr. 1986. Ethansalz 97/100: Examination of the acute oral toxicity of male and female Wistar rats. Hoechst Corporation. Report No. 89.1099. (in German)

Reliability: (1) Valid without restriction. Well documented GLP study.

5.1.2 Acute Inhalation Toxicity

Remark: No data available

5.1.3 Acute Dermal Toxicity

Remark: Refer to section 5.2.1 for data on the dermal exposure of sodium isethionate to rabbits.

5.1.4 Acute Toxicity, other Routes

Remark: Not a required HPV endpoint.

5.2 Corrosiveness and Irritation

5.2.1 Skin Irritation

(a)

Species: rabbit (New Zealand albino)

Concentration: 0.5 g

Exposure Time: 4 hours

Number of Animals: 3

PDII: 0.0

Result: not irritating

EC classificat.: not classified

Method: In accordance with OECD Guide-line 404 and EEC Directive 92/69, Publication No. L 383A, B.4. Young adult rabbits were identified individually with an ear tattoo and housed in individual fully air-conditioned rooms at a temperature of 22±2°C and relative humidity of 30-70% and under a 12 hour light/dark photoperiod. Each

animal was housed individually in stainless steel wire cages and provided approximately 250 mL tap water and 130 g food per animal per day. At least 24 hours before the test, the fur was removed by clipping the dorsal part of the trunk of the animals. The test substance was applied in a single dose to the intact skin, covered with a test patch and secured with a semiocclusive dressing. After four hours the patch and test substance was removed with Lutrol. Untreated sites on the same animals acted as negative controls.
A dose of 0.5 g of the unchanged solid test substance moistened with Aqua Bidest was used. Animal weights at the beginning of the study were 3.48, 3.60 and 3.71 kg for the three animals (two male and one female). Readings were taken at 1, 24, 48 and 72 hours and scored for presence and severity of erythema/eschar formation and edema formation.

Year Conducted: 1996 **GLP:** yes

Test substance: Lutensit A-IS Pulver (Sodium 2-Hydroxyethylsulfonate) [Sodium isethionate]; CAS No. 1562-00-1; Barrel No. 60; white powder; purity 95.3%; miscible up to 10 g/L

Results: Barely perceptible erythema (score of 1) was observed in all three animals at the 1 hour observation time, but this had completely disappeared by 24 hours. All the remaining scores were 0 (no effect) for the rest of the study.

Remarks: The stability of the test substance over the duration of the test was confirmed by analysis. Results are reported as nominal dose.

Source: Kuehlem, Dr. 1998. Study on the Acute Dermal Irritation/Corrosion of Lutensit A-IS Pulver in the Rabbit. BASF Corporation, Laboratory Project No. 18H0094/962031. (English translation of German report)

Reliability: (1) Valid without restriction. Well documented GLP study.

(b)
Species: rabbit (New Zealand albino)
Concentration: 500 mg (0.1 mL)
Exposure Time: 4 hours
Number of Animals: 3
PDII: 0.0
Result: not irritating
EC classificat.: not classified

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion." Young adult rabbits were identified individually with an ear tattoo and housed in individual fully air-conditioned rooms at a temperature of 20±3°C and relative humidity of 50±20% and under a 12 hour light/dark photoperiod. Animals were provided drinking water and food *ad libitum*. At least 24 hours before the test, the fur was removed by clipping the dorsal part of the trunk of the animals. The test substance was applied in a single dose to the intact skin, covered with a 2 x 2 cm test patch and secured with a semiocclusive dressing. After four hours the patch was removed and the area rinsed with lukewarm water. Untreated sites on the same animals acted as negative controls. Animal weights at the beginning of the study ranged from 2.6-2.8 kg. Readings were taken at 30-60 minutes, and 24, 48 and 72 hours and scored for presence and severity of erythema/eschar formation and edema formation.

Year: 1986 **GLP:** yes

Test substance: Sodium 2-hydroxyethane sulfonic acid (1562-00-1); minimum purity 97%; white powder

Results: No incidence of erythema/eschar or edema was observed at any time during the study.

Remarks: The test substance is not irritating to the skin.

Source: Hofmann, Dr. and Hollander, Dr. 1986. Ethansalz 97/100. Examination of skin irritation in rabbit. Hoechst Corporation. Report No. 86.1042. (in German)
Reliability: (1) Valid without restriction. Well documented GLP study.

5.2.2 Eye Irritation

(a)
Species: rabbit (New Zealand albino)
Concentration: 0.1 mL bulk volume (about 58 mg)
Exposure Time: 24 hours
Number of Animals: 3
PDII: 0.0 (corneal opacity, iris, and chemosis); 0.3 (conjunctival redness)
Result: not irritating
EC classificat.: not classified
Method: In accordance with OECD Guide-line 405 and EEC Directive 92/69, Publication No. L 383A, B.5. Young adult rabbits were identified individually with an ear tattoo and housed in individual fully air-conditioned rooms at a temperature of 22±2°C and relative humidity of 30-70% and under a 12 hour light/dark photoperiod. Each animal was housed individually in stainless steel wire cages and provided approximately 250 mL tap water and 130 g food per animal per day. Both eyes of the animals were examined before application of the test material for signs of pre-existing irritation, reaction or abnormality. A single application of the test material was given to the conjunctival sac of the right eyelid, which was washed out with tap water after 24 hours. The left eye was left untreated as a negative control. The application volume was 0.1 mL bulk volume, which is approximately 58 mg of the test substance. Animal weights at the beginning of the study were 3.48, 3.60 and 3.71 kg for the three animals (one male and two females). Readings were taken at 1, 24, 48 and 72 hours and scored for corneal opacity, conjuntival redness, chemosis, and iris effects.
Year Conducted: 1996 **GLP:** yes
Test substance: Lutensit A-IS Pulver (Sodium 2-Hydroxyethylsulfonate) [Sodium isethionate]; CAS No. 1562-00-1; Barrel No. 60; white powder; purity 95.3%; miscible up to 10 g/L
Results: No effects were observed for corneal opacity or iris. Minor chemosis (score of 1) was observed at the 1 hour period only and disappeared shortly thereafter. Minor conjunctival redness was observed at the 1 and 24 hour periods but not thereafter. Conjunctival discharge (score of 2) was observed at 1 hour only.
Remarks: The stability of the test substance over the duration of the test was confirmed by analysis. Results are reported as nominal dose.
Source: Kuehlem, Dr. 1998. Study on the Acute Eye Irritation of Lutensit A-IS Pulver in the Rabbit. BASF Corporation, Laboratory Project No. 11H0094/962032. (English translation of German report)
Reliability: (1) Valid without restriction. Well documented GLP study.

(b)
Species: rabbit (New Zealand albino)
Concentration: 100 mg (0.1 volume)
Exposure Time: 24 hours
Number of Animals: 3
PDII: 0.0 (corneal opacity, iris); 0.7 (conjunctival redness); 0.2 (conjunctival swelling)

Result: not irritating
EC classificat.: not classified
Method: OECD Guide-line 405 "Acute Eye Irritation/Corrosion." Young adult rabbits were identified individually with an ear tag and housed in air-conditioned rooms at a temperature of 20±3°C and relative humidity of 50±20% and under a 12 hour light/dark photoperiod. Each animal was housed individually in stainless steel wire cages and provided drinking water and food *ad libitum*. Both eyes of the animals were examined before application of the test material for signs of pre-existing irritation, reaction or abnormality. A single application of the test material was given to the conjunctival sac of the left eyelid, which was washed out with saline after 24 hours. The right eye was left untreated as a negative control. The application volume was 0.1 mL bulk volume. Animal weights at the beginning of the study ranged from 2.2-3.0 kg. Readings were taken at 1, 24, 48 and 72 hours and scored for corneal opacity, conjuntival redness, chemosis, and iris effects.
Year: 1986 **GLP:** yes
Test substance: Sodium 2-hydroxyethane sulfonic acid (1562-00-1); minimum purity 97%; white powder
Results: Swelling of the lids and redness of the conjunctiva and iris was observed one hour after application. A clear discharge was also observed. These symptoms were reduced at 24 hours and disappeared by 48 hours. The table below summarizes the symptoms observed:

Time post application	**1 hour**			**24 hours**			**48 hours**			**72 hours**		
Animal Number	**1**	**2**	**3**	**1**	**2**	**3**	**1**	**2**	**3**	**1**	**2**	**3**
Swelling	4	3	2	1	1	0	0	0	0	0	0	0
Redness	1	1	2	2	1	1	1	0	1	0	0	0
Iris	0	0	1	0	0	0	0	0	0	0	0	0
Corneal Opacity	0	0	0	0	0	0	0	0	0	0	0	0

Remarks: The test substance is not considered irritating according to the criteria.
Source: Hofmann, Dr. and Hollander, Dr. 1986. Ethansalz 97/100. Examination of eye irritation in rabbit. Hoechst Corporation. Report No. 86.1041. (in German)
Reliability: (1) Valid without restriction. Well documented GLP study.

5.3 Sensitization

Remark: No specific animal studies are available, however, the sodium cocoyl isethionate (SCI) dossier reports three studies on SCI products that contained 10% sodium isethionate. No sensitization was observed in any of these studies.

5.4 Repeated Dose Toxicity

Remark: Specific studies addressing repeated dose toxicity were not available.

5.5 Genetic Toxicity 'in Vitro'

(a)

Type: Bacterial reverse mutation assay (Ames test)

System of testing: *Salmonella typhimurium* TA 98, TA 100, TA 1535, TA 1537, TA 1538

Concentration: 4 to 5000 ug/plate

Metabolic activation: with and without

Result: negative

Method: OECD Guideline 471 "Genetic Toxicology: *Salmonella thyphimurium* reverse mutation assay." The assay was performed in two phases. The first phase was performed with all tester strains to establish the appropriate dose range. The test material were plated, one plate per dose, with an overnight culture of TA 100 on selective minimal agar in both the presence and absence of microsomal enzymes. The second phase is the initial mutagenicity assay and the confirmatory mutagenicity assay. The test material was tested at six dose levels along with the appropriate vehicle and positive controls on tester strains TA 98, TA100, TA 1535, TA 1537 and TA 1538 in the presence and absence of S-9 mix. All dose levels and controls were plated in triplicate. The dose levels reported are actual measured concentrations, adjusted for purity. Following the preincubation, 2.0 mL of selective top agar was added to each culture tube and the mixture was vortexed and overlaid onto the surface of 25 mL of minimal bottom agar. After solification, the plates were inverted and incubated for 48 hours at 37 ± 2°C and the colonies were counted. The condition of the bacterial lawn was evaluated for evidence of toxicity; any observed was scored relative to the vehicle control plate. For all replicate platings, the mean number of revertants per plate was calculated. Two independent experiments were performed.

Year: 1992 **GLP:** yes

Test substance: Sodium 2-hydroxyethane sulfonic acid (1562-00-1); purity 99.6%; white powder

Remarks: No toxicity was observed at doses from 4 to 10,000 µg/plate in the preliminary studies. For mutagenicity testing, 5000 µg/plate was chosen as the highest dose. No significant increases in the revertant colonies was observed in any of the tester strains either in the absence or presence of S-9 mix. No dose dependent effect was obtained. The test substance is not mutagenic.

Source: Stammberger, I. 1993. Ethansalz 97/100: Study of the mutagenic Potential in strains of *Salmonella typhimurium* (Ames Test) and *Escherichia coli*. Hoechst Corporation. Report No. 92.0810.

Reliability: (1) Valid without restriction. Well documented GLP study.

(b)

Type: Bacterial reverse mutation assay (Ames test)

System of testing: *Escherichia coli* WP2uvrA

Concentration: 4 to 5000 ug/plate

Metabolic activation: with and without

Result: negative

Method: OECD Guideline 472 "Genetic Toxicology: *Escherichia coli* reverse mutation assay." The assay was performed in two phases. The first phase was performed to establish the appropriate dose range. The test material were plated, one plate per dose, with an overnight culture of *E. coli* WP2uvrA on selective minimal agar in both the presence and absence of microsomal enzymes. The second phase is the initial mutagenicity assay and the confirmatory mutagenicity assay. The test material was tested at six dose levels along with the appropriate vehicle and positive controls on *E. coli* WP2uvrA in the presence and absence of S-9 mix. All dose levels and controls were plated in triplicate. The dose levels reported are actual measured concentrations, adjusted for purity. Following the preincubation, 2.0 mL of selective top agar was added to each culture tube and the mixture was vortexed and overlaid onto the surface of 25 mL of minimal bottom agar. After solification, the plates were inverted and incubated for 48 hours at 37 ± 2°C and the colonies were counted. The condition of the bacterial lawn was evaluated for evidence of toxicity; any observed was scored relative to the vehicle control plate. For all replicate platings, the mean number of revertants per plate was calculated. Two independent experiments were performed.

Year: 1992 **GLP:** yes

Test substance: Sodium 2-hydroxyethane sulfonic acid (1562-00-1); purity 99.6%; white powder

Remarks: No toxicity was observed at doses from 4 to 10,000 µg/plate in the preliminary studies. For mutagenicity testing, 5000 µg/plate was chosen as the highest dose. No significant increases in the revertant colonies was observed in any of the tester strains either in the absence or presence of S-9 mix. No dose dependent effect was obtained. The test substance is not mutagenic.

Source: Stammberger, I. 1993. Ethansalz 97/100: Study of the mutagenic Potential in strains of *Salmonella typhimurium* (Ames Test) and *Escherichia coli*. Hoechst Corporation. Report No. 92.0810.

Reliability: (1) Valid without restriction. Well documented GLP study.

5.6 Genetic Toxicity 'in Vivo'

Remark: Not required. *In vitro* studies did not reveal any indication of mutagenicity.

5.7 Carcinogenicity

Remark: Not an HPV endpoint. Data from genotoxicity studies do not suggest any carcinogenicity concern.

5.8 Toxicity to Reproduction

Remarks: Specific studies addressing the reproductive toxicity endpoint were not available.

5.9 Developmental Toxicity/Teratogenicity

Remark: Specific studies addressing the developmental toxicity endpoint were not available.

5.10 Other Relevant Information

Remark: Mammalian toxicity data for sodium cocoyl isethionate (SCI) from repeated dose studies conducted via both oral and dermal routes show no significant systemic toxicity. These repeated dose data are relevant for read across to SI as ADME studies indicate that SCI is metabolized to SI by hydrolysis of the ester bond in SCI (see Howes 1975).

5.11 Experience with Human Exposure

Memo: Sodium isethionate (SI) has been used in consumer products for many years without reported incident. In addition, sodium isethionate is a component of the products tested with sodium cocoyl isethionate (SCI), so data from those human exposure studies may also provide information useful for evaluating the consumer safety of SI.

ECOSAR v.0.99g

EPI Suite v3.12.

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Hofmann, Dr. and Hollander, Dr. 1986. Ethansalz 97/100. Examination of skin irritation in rabbit. Hoechst Corporation. Report No. 86.1042. (in German)

Hofmann, Dr. and Hollander, Dr. 1986. Ethansalz 97/100. Examination of eye irritation in rabbit. Hoechst Corporation. Report No. 86.1041. (in German)

IUCLID Data Set. CAS No. 1562-00-1. Sodium 2-hydroxyethane sulphonate. February 18, 2000. Year 2000 CD-ROM Edition.

Kuehlem, Dr. 1998. Study on the Acute Dermal Irritation/Corrosion of Lutensit A-IS Pulver in the Rabbit. BASF Corporation, Laboratory Project No. 18H0094/962031. (English translation of German report)

Kuehlem, Dr. 1998. Study on the Acute Eye Irritation of Lutensit A-IS Pulver in the Rabbit. BASF Corporation, Laboratory Project No. 11H0094/962032. (English translation of German report)

Kuehlem, Dr. 1998. Study on the Acute Oral Toxicity of Lutensit A-IS Pulver in Rats. BASF Corporation, Laboratory Project No. 10A0094/961030. (English translation of German report)

Maisch, Dr. 1997. Determination of the acute toxicity of Lutensit A-IS Pulver to the water flea *Daphnia magna* STRAUS. BASF Corporation, Project No. 96/0154/50/1. (English translation of German report)

Maisch, Dr. 1997. Determination of the inhibitory effect of Lutensit A-IS Pulver on cell division of the green alga *Scenedesmus subspicatus*. BASF Corporation, Project No. 96/0154/60/1. (English translation of German report)

Munk, R. 1998. Lutensit A-IS Pulver: Acute Toxicity Study on the Zebra Fish (*Brachydanio rerio* HAM. And BUCH.) in a Static System (96 hours). BASF Corporation, Laboratory Project Number 17F0094/965020 (English translation of German report).

Noack, M. 2005. Hostapon SI 57%: Acute Immobilisation Test (Static, 48 h) to Daphnia magna STRAUS, Limit-Test. Dr. U. Noack Laboratorien, Study No. DA199811. Sponsored by Clariant GmbH.

Stammberger, I. 1993. Ethansalz 97/100: Study of the mutagenic Potential in strains of *Salmonella typhimurium* (Ames Test) and *Escherichia coli*. Hoechst Corporation. Report No. 92.0810.

Taeger, Dr. 2006. Study of the biodegradability of Lutensit A-IS Powder in the DOC decrease (die away) test. BASF Corporation, Laboratory Project No.96/0154/21/1 (English translation of German report, original report date 1996).

Zok, S. 1996. Ethansalz 97/100: 96-hour acute toxicity study in Zebra Fish (*Brachydanio rerio*). Hoechst Corporation, Report No. 96.0895

7.1 Risk Assessment

Memo: See sodium isethionate assessment plan. In addition, several of the studies in the sodium cocoyl isethionate dossier may also be relevant because they were conducted on products that also contained SI.