201-16599B

I U C L I D

D a t a S e t

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 x 10^{6} molecule/cm^{3}
Rate constant: 5.3097 x 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.

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.

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)

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.