GreenScreen® Chemical Assessment

Sodium laureth sulfate *(CAS# 68891-38-3)*

Method Version: GreenScreen® Version 1.4

Assessment Details:

Assessment Type:	Certified
Assessment Prepared By:	WAP Sustainability Consulting, LLC (Eric Rosenblum Ph.D. DABT and Donald K. Ward, NSF International)
Assessment Prepared For:	Public Benefit
Date Assessment Completed:	April 24th, 2019
Assessment Expiration Date:	April 24th, 2024
Assessor Type:	Licensed GreenScreen® Profiler

1701 Market St., Chattanooga, TN 37421
info@wapsustainability.com • 855.452.2522

GREENSCREEN BENCHMARK™ SUMMARY:

This chemical assessment report includes a GreenScreen Benchmark™ score and results for Sodium laureth sulfate (CASRN 68891-38-3) only. This chemical assessment does not address potential residuals or other contaminants that may be associated with Sodium laureth sulfate such as ethylene dioxide and 1,4 Dioxane.

No marketing claims can be made without licensing through Clean Production Action.

GreenScreen Benchmark Score:
Sodium laureth sulfate was assigned a GreenScreen® Benchmark Score of 2 ("Use but Search for Safer Substitutes") as it has very high Group II human toxicity (IrE). This corresponds to GreenScreen® benchmark classification 2f in CPA 2018. Data gaps (DG) exist for endocrine activity (E), repeat and single dose neurotoxicity (N), and respiratory sensitization (SnR). As outlined in CPA (2018) Section I 11.6.2 (Step b –Determine the final Benchmark score), Sodium laureth sulfate meets requirements for a GreenScreen® Benchmark Score of 2 despite the hazard data gaps. In a worst-case scenario, if Sodium laureth sulfate were assigned a High score for data gap endocrine activity it would be categorized as a Benchmark 1 Chemical.

HAZARD CLASSIFICATION SUMMARY

Table 1. GreenScreen Hazard Summary Table:[1]

GreenScreen Hazard Summary Table for Sodium laureth sulfate																					
Group I Human					**Group II and II* Human**										**Ecotox**		**Fate**		**Physical**	
Carcinogenicity	**Genotoxicity/Mutagenicity**	**Reproductive Toxicity**	**Developmental Toxicity**	**Endocrine Activity**	**Acute Toxicity**	**Systemic Toxicity**		**Neurotoxicity**		**Skin Sensitization***	**Respiratory Sensitization***	**Skin Irritation**	**Eye Irritation**		**Acute Aquatic Toxicity**	**Chronic Aquatic Toxicity**	**Persistence**	**Bioaccumulation**	**Reactivity**	**Flammability**
						single	repeat*	single	repeat*	*	*									
L	**L**	**L**	**L**	DG	**L**	**L**	**L**	DG	DG	**L**	DG	**H**	*vH*		**H**	**H**	**vL**	*vL*	*L*	**L**

Note: Hazard levels (Very High (vH), High (H), Moderate (M), Low (L), Very Low (vL)) in *italics* reflect lower confidence in the hazard classification while hazard levels in **BOLD** font reflect higher confidence in the hazard classification. Group II Human Health endpoints differ from Group II* Human Health endpoints in that Group II Human Health endpoints have four hazard scores (i.e., vH, H, M and L) instead of three (i.e., H, M and L), and are based on single exposures instead of repeated exposures. Group II* Human Health endpoints are indicated by an * after the name of the hazard endpoint or after "repeat" for repeated exposure sub-endpoints.

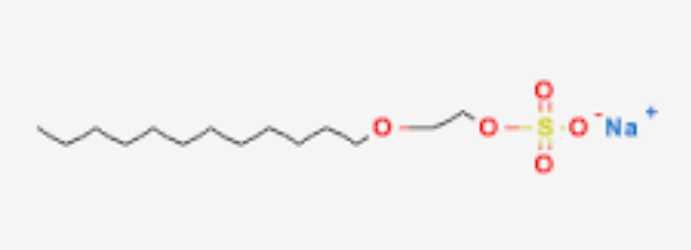
[1] See Appendix A for a glossary of hazard endpoint acronyms.

SCOPE OF ASSESSMENT

Sodium laureth sulfate (CASRN 68891-38-3):

Also Called (List Synonyms):
Dodecyl sodium sulfate
PEG-(l-4) lauryl ether sulfate, sodium salt
Polyethylene glycol (1-4) lauryl ether sulfate, sodium salt
Poly(oxy- l ,2-ethanediyl), o-sulfo-co-(dodecyloxy)-, sodium salt
Polyoxyethylene (1-4) lauryl ether sulfate, sodium salt
Sodium PEG lauryl ether sulfate
Sodium polyoxyethylene lauryl ether sulfate
Sodium polyoxyethylene lauryl sulfate
Alcohols, C12-14, ethoxylated, sulfates, sodium salts

Chemical Structure:



Suitable analogs or moieties of chemicals used in this assessment (CASRN(s)):
For each analog, please include the hazard endpoint(s) evaluated and the rationale for selecting the analog(s). If a suitable analog(s) was not identified, please describe what analog(s) was considered and your rationale for not using the analog.

Chemical Structure(s) of suitable analog(s) and/or moieties:
The alcohol ethoxysulphate family used within this assessment follows the approach used by the 2003 Alcohol ethoxysulfate risk assessment (HERA 2003). Specifically, the alcohol ethoxysulphate family is defined for purposes to encompass commercial grades of linear-type primary alcohol ethoxysulphates containing AES components of basic structure CnH2n+O(C2H4O)mSO3X) where n=10-18 and m = 0-8 and X = sodium, ammonium or triethanolamine (TEA).

For Inorganic Chemicals and relevant particulate organics (*if not relevant, list NA*)
Define Properties:
1. Particle size (e.g., silica of respirable size) NA
2. Structure (e.g., amorphous vs. crystalline) NA
3. Mobility (e.g., water solubility, volatility) See Persistence section
4. Bioavailability
   - Absorption: Oral absorption 100%, Dermal absorption 0.9%. (ECHA 2019)

Identify potential applications/functional uses of the chemical:
Sodium laureth sulfate is used in cosmetic products as cleansing agents, emulsifiers, stabilizers, and solubilizers (CIR 1983).

Table 2. Environmental Transformation Products Summary

Life Cycle Stage	Transformation Pathway	Environmental Transformation Product	CAS #	Feasible (Yes or No)	Relevant (Yes or No)	GreenScreen List Translator Score or GreenScreen Benchmark Score
End of Life	Ultimate biodegradation	CO2	124-38-9	Y	N	LT-UNK
		H20	7732-18-5	Y	N	BM4

Report rationale for each determination as to whether an identified environmental transformation product is feasible and relevant:

Based upon BOD and evolved CO^2 data, AES undergo rapid ultimate biodegradation to CO_2 'and H_20. (Little 1991). These two ultimate biodegradation products are not considered relevant based on GreenScreen guidance (Section 14.3.2 Step 2; GreenScreen Method 2015).

HAZARD CLASSIFICATION SUMMARY

GROUP I HUMAN HEALTH EFFECTS (GROUP I HUMAN)

Carcinogenicity (C): *L*

Sodium laureth sulfate was assigned a hazard classification level of low with low confidence for carcinogenicity based on negative findings in dermal application studies and intraperitoneal exposure studies. Although no specific carcinogenicity study is available on alkyl ether sulfates (AES), the scientific weight of the evidence suggests that members of the AES category do not cause carcinogenic effects. This expert judgment takes account of the complete absence of genotoxicity and structural alerts for genotoxicity and carcinogenicity for all members of AES category as well as their overall low toxicity in repeated dose toxicity studies. The low hazard conclusion is based on weight of evidence and based on the alkyl ether sulfates chemical class and therefore is reported with low confidence.

Data

- Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists

- Measured Data

  ECHA 2019
  - The alkyl ether sulfates (AES) reported within the category show similar structural, physico-chemical, environmental and toxicological properties. The approach of grouping different AES for the evaluation of their effects on human health and the environment was also made by the Danish EPA (2001) and HERA (2003), supporting the read-across approach between structurally related AES. Although no specific carcinogenicity study is available on alkyl ether sulfates (AES), the scientific weight of the evidence suggests that members of the AES category do not cause carcinogenic effects. This expert judgment takes account of the complete absence of genotoxicity and structural alerts for genotoxicity and carcinogenicity for all members of AES category as well as their overall low toxicity in repeated dose toxicity studies.
  - Several studies investigating the genetic toxicity of different AES *in vitro* and *in vivo* have shown that AES are not genotoxic. Moreover, the repeated dose toxicity tests revealed no substance-related adverse effects indicative for carcinogenicity such as preneoplastic lesions (e.g. hyperplasia or metaplasia). Furthermore, AES are metabolized to physiologically occurring metabolites, which chemically behave like in the same way as their natural counterparts. The systemic toxicity of the compounds in this category is predicted to be very low, based on the known properties of the predictable metabolites. Based on this weight of evidence approach members of the AES category does not cause carcinogenicity.

  HERA 2003
  - In a 2-year study, rats (20/sex/group) were administered $C_{12}AE_3S$ in the drinking water at a concentration of 0.1%. At termination, survival, growth, food consumption,

body weights, clinical laboratory findings, hematology and urinalyses were all comparable in control and treated animals. The only unusual findings were slight, but consistently higher water consumption by all rats receiving the test compound in their drinking water and a significant difference in the empty cecum to body weight ratio of females. Absolute organ weights were all comparable to controls and no consistent gross or histopathology was found. Generally, pathological findings for controls and treated rats after two years on test were varied and consisted predominantly of incidental findings attributable to advanced age. Various types of benign and malignant tumors were found in both groups. The frequency of tumors in the treated group was not significantly different from that of control animals.

- No indications of an increased incidence in tumors were noted in a 2-year chronic feeding study in rats in which C12 AE3S was given at 0, 0.1 or 0.5% in the diet for 2 years. An occasional tumor (type and incidence unspecified) was found in various groups. The tumors were characterized as “typical” of those commonly found in aged rats and did not appear to be associated with the ingestion of AES
- An 5% aqueous solution of C_{12}AE3S (0.1ml) was applied twice weekly on the skin of 30 female Swiss mice. No papillomas or other tumors were found under these exposure conditions.
- In its report to the Soap and Detergent industry, Arthur D. Little reported on a study in which an aqueous solution of 18.5% C16-18AES and 15.6% LAS was applied 3 times a week on the skin of Swiss ICR mice for 18 months. Under these conditions, the test solutions did not induce any carcinogenic response either on the skin or systemically.

- Estimated Data: none

Mutagenicity/Genotoxicity (M): L

Sodium laureth sulfate was assigned a hazard classification level of Low for Mutagenicity/Genotoxicity based on no indication of genetic toxicity in both *in vitro* and *in vivo* studies. In addition, there was no indication of genetic toxicity in both *in vitro* and *in vivo* studies for a broad range of structurally different alcohol ethoxylates. Most of these studies were performed in accordance with GLP and following OECD guideline methodologies. The low hazard conclusion is based on study data specific to the chemical and broad range of structurally different alcohol ethoxylates therefore is reported with high confidence.

Data

- Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists

- Measured Data
  ECHA 2019
  - *In vitro* gene mutation: Bacterial reverse mutation assay (Ames test / OECD guideline 471): negative
  - *In vitro* mammalian cell gene mutation assay (MLA / OECD guideline 476): negative
  - *In vivo*: Mammalian Bone Marrow Chromosome Aberration Test (OECD 475):

negative

HERA 2003

- In an OECD method 471 and GLP compliant study Salmonella typhimurium strains TA98, TA100, TA1535 and TA 1537 were treated with the triisopranolammonium salt of C12-14AE2S in the Ames test plate incorporation assay as well as the preincubation method. Dose levels covering the range of 1 to 5000 µg/plate, in triplicate both with and without the addition of a metabolizing system (Aroclor 1254 induced rat liver S9 mix) were employed. All 4 bacterial strains exhibited mutagenic responses to the appropriate positive control substances. Solvent controls were also tested with each strain and the mean numbers of spontaneous revertants were in an acceptable range. Mutagenic activity of the test compound to any of the tester strains was not observed with and without metabolic activation. It was therefore concluded that under the chosen test conditions, the triisopranolammonium salt of C12-14AE2S is not a bacterial mutagen.
- The majority of the studies evaluated the mutagenicity of AES in Salmonella typhimurium strains TA98, TA100, TA1535, TA 1537 and TA 1538. One study, however, evaluated the mutagenicity of NaC12-15E3S in presence and absence of a metabolic activation system in the Escherichia coli strains WP2 and WP2uvrA, in addition to the Salmonella typhimurium strains. Also, in these E. coli strains, the tested AES compounds were not mutagenic under the test conditions. In all tested systems, AES were not found to be mutagenic to bacterial systems.
- The mutagenic activity of NaC12-15AE3S was further evaluated in a Saccharomyces gene conversion assay. In this study, it was concluded that the addition of NaC12-15AE3S to liquid suspension cultures of Saccharomyces cerevisiae JD1 with or without metabolic activation did not induce a consistent increase in mitotic gene conversion at either gene locus in two replicate experiments.
- AES was examined for mutagenic activity by assaying for the induction of trifluorothymidine resistant mutants in L5178Y TK+/- mouse lymphoma cells after in vitro treatment in the absence and presence of S9 metabolic activation. Under the reported experimental conditions, it was concluded that in the presence and absence of metabolic activation, the test material NaC12-14AE2S did not induce gene mutations in L5178Y TK+/- mouse lymphoma cells. This study was conducted in compliance with OECD method 476 and GLP regulations.
- The ability of NaC12-15E3S to induce chromatid and chromosome aberrations was studied in rat liver cells. In slide cultures of rat liver cells exposed to culture medium containing NaC12-15E3S at concentrations of 25, 50 and 100 µg/ml the frequency of chromatid and chromosome aberrations did not differ significantly from that of the controls cultures.
- No morphological cell transformations were observed in Syrian golden hamster embryo cells exposed in culture to concentrations up to 50 mg/ml C12-13E2.5S.
- In an *in vitro* transformation study with NaC12-15E3S, the transforming activities of NaC12-15E3S and 1,4-dioxane were determined using cultured C3H 10T1/2 mouse embryo fibroblasts as the target cell population. Monolayer cell cultures were incubated for 24 hours in growth medium containing NaC12-15E3S or 1.4-dioxane. Transformation frequencies were assessed by counting the number of actively dividing, darkly stained cell foci per dish, 3 or 4 weeks after test compound treatment. In conclusion, there was no evidence to suggest that either NaC12-15E3S or 1,4-dioxane increased the frequency of 10T1/2 mouse embryo fibroblasts under the experimental conditions described.

- NaC12-15E3S has been evaluated in an alkaline elution assay. In this screen which aims to measure DNA single-strand breaks induced in DNA by reaction with electrophiles, NaC12-15E3S did not cause measurable DNA-strand damage when administered to Wistar rats as a single oral dose of 2.5 ml/kg (equals about half of the LD50 of NaC12-15E3S) for an exposure period of 6 hours. Based on this result it was concluded that neither NaC12-15E3S nor its in situ generated metabolites have any effect upon the integrity of rat liver DNA *in vivo* under the conditions of the test.
- In a series of studies with a 55% AES:45% LAS mixture, no significant differences from control values were noted in a dominant lethal study or *in vivo* or *in vitro* cytogenicity studies.
- In the dominant lethal assay, male mice were orally administered either 100, 150, or 200 mg/kg subacutely or 500, 750, or 1000 mg/kg acutely of the surfactant mixture. No significant differences from water-dosed controls were observed in the mutagenic index.
- No significant differences in chromosomal anomalies were found in bone marrow cells of male rats given 40, 500, or 1000 mg/kg of the surfactant mixture orally, then killed 18, 24 or 48 hours post-dosing.
- Human leukocytes incubated for 18, 24, or 48 hours with 4, 40 or 200 µg/l of the surfactant mixture exhibited no increased incidence of chromosomal anomalies above the water control group.
- A published *in vivo* reported that the incorporation of C12-15AES into the diet of rats at a maximum tolerated dose (1.13% active ingredient) for 90 days had no effect on the chromosome of rat bone marrow

- Estimated Data: none

Reproductive Toxicity (R): L

Sodium laureth sulfate was assigned a hazard classification level of low with high confidence for reproductive toxicity based on a rat oral exposure study reporting that the compound did not adversely affect reproduction with a NOAEL for reproductive effects of > 300 mg/kg. In addition, numerous studies reported for other alcohol ethoxysulphates indicate no effects to reproductive organs in OECD reproductive/developmental toxicity screening studies and repeat dose studies in multiple species. The low hazard conclusion is based on study data specific to the chemical and supported by data for alcohol ethoxysulphates therefore is reported with high confidence.

Data

- Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists

- Measured Data

  ECHA 2019
  - In the available subchronic and chronic toxicity studies on various AES the primary sex organs of the males and females did not show evidence for treatment-related adverse effects. The observed reduced triglyceride levels (female) and increased percentage neutrophil counts (males) were slight and within the range of the

historical control data.

HERA 2003

- As part of a chronic feeding study, 10 rats/sex/group fed diets containing 0.1% of C12AES were mated after 14 weeks on the test. The F1 generation was maintained on the parental diet and mated at 100 days of age. The F2 generation was fed the same diet for 5 weeks, and then killed. No adverse effects on fertility, lactation, litter size or survival and growth of the offspring were seen. Hematological, biochemical and histopathological findings were comparable to controls. From this study it can be concluded that the NOEL for reproductive toxicity is estimated to be greater than 50 mg/kg bw/day. This estimation was based on the assumption of a mean adult rat body weight of 0.4kg and a water consumption of 30 ml/day [US Environmental Protection Agency, 1978]. system.
- No adverse parental toxicity or significant differences in either litter parameters or viability of offspring were noted in two generations of rats fed diets containing either 0.1% C12AES or 1% (reported to equal an exposure of 800 mg/kg/day) of a detergent formulation containing 55%TE3S and 45% LAS.
- In available subchronic and chronic toxicity studies on various AES (NaC12-14AE2S, CaC123-15AE3S, C12AE3S), the primary sex organs of the males and females did not show evidence for treatment-related adverse effects as indicated by organ weight differences, gross examination, and microscopic histology examination at the highest tested exposure levels of 250 mg/kg bw/d
- Further information can be deduced from a two-generation reproduction study with NaC12- 14AE2S. This GLP-study followed the OECD guideline method 416. Four groups of thirty male and thirty female Sprague Dawley rats (strain Crl:CD(SD)BR) (F0 generation) were dosed via the drinking water. Concentrations used were 0 (control), 0.03, 0.1 and 0.3 %, which corresponded to daily doses of ca. 0, 30, 100 and 300 mg/kg/day. There were some changes indicative of parental toxicity in the group treated with 0.3 % of the test substance, which were characterized by reduced straight line velocity of the sperm. The observed reduced triglyceride levels (female) and increased percentage neutrophil counts (males) were slight and within the range of the historical control data. There was evidence of toxicity on pup development at this dose level that was characterized by an increase in the time taken for sexual development of the male (not significant) and female (significant) offspring. No other developmental parameters were affected. There were some changes seen in reduced straight-line velocity of the sperm, reduced trigylceride levels (female) and increased percentage neutrophil counts (males) in the group treated at 0.1 %. All the changes were either not statistically significant or within the range of the historical control data. In summary, there was no effect of treatment at any dose level on reproduction of the parents or offspring (NOAEL > 3 %; > 300 mg/kg/day)

- Estimated Data: none

Developmental Toxicity incl. Developmental Neurotoxicity (D): L

Sodium laureth sulfate was assigned a hazard classification level of low with high confidence for developmental toxicity incl. developmental neurotoxicity based on no cumulative toxicity observed in pregnant rats and the absence of any embryotoxic or teratogenic potential at the highest tested dose levels of 1000 mg/kg body weight. In addition, toxicity studies available for other alcohol ethoxysulphates have confirmed the

lack of potential adverse effects on the developing fetus. The low hazard conclusion is based on study data specific to the chemical and therefore is reported with high confidence.

Data

- Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists

- Measured Data

  HERA 2003
  - NaC12-14AE2S was tested in a segment II embryotoxicity study. The purpose of the study was to assess the effects of orally administered NaC12-14AE2S on embryonic and fetal development in pregnant CD-rats. The study followed the guidelines of OECD method 414 “Teratogenicity” and complied with the OECD principles of GLP. In this study, NaC12-14AE2S was administered orally by gavage at dose levels of 0, 100, 300, and 1000 mg/kg body weight once daily from day 6 to day 15 of gestation. Each group consisted of at least 24 female rats. A standard dose volume of 10 ml/kg body weight was used and the control animals were dosed with the vehicle alone over the period described. Clinical condition and reaction to treatment were recorded at least once daily. Body weights were reported for days 0, 6, 16 and 20 of gestation. All surviving females were sacrificed on day 20 of gestation and the foetuses were removed by caesarean section. At necropsy the females were examined macroscopically and live foetuses were weighed, sexed and examined for visceral and skeletal abnormalities. In summary, the results of the study showed that repeated oral administration (day 6 – day 15 post coitum) of NaC12-14AE2S to pregnant rats did not cause symptoms of cumulative toxicity up to a dose level of 1000 mg/kg/day. No compound related symptoms were observed and no treatment-related abnormalities were found at necropsy of the females. All females had viable foetuses. Pre-implantation loss, postimplementation loss, mean number of resorptions, embryonic deaths, total foetuses, mean foetal placental and uterus weights were not affected by the treatment. Foetal sex ratio was comparable in all groups. There were no treatment-related foetal abnormalities at necropsy and no treatment-related effects in the reproduction data. In conclusion, in the described embryotoxicity study, NaC12-14AE2S was not cumulatively toxic to pregnant rats and did not reveal any teratogenic potential at the tested dose levels. Thus, based on the available information, the NOAEL for teratogenicity and developmental toxicity are assessed to be greater than 1000 mg/kg bw/day. NaC12-15AE3S was administered orally by gavage to pregnant
  - Colworth-Wistar rats at dose levels of 0, 375 and 750 mg/kg/day once daily from day 6 to 15 of gestation. Two different samples of the test material were tested. Fifteen (15) animals were used per dose group, 10 for dissection and 5 for natural parturition. Throughout the study, the females were monitored for signs of toxicity. Upon necropsy, fetal toxicity was determined by evaluating pre-implantation and post-implantation fetal loss and fetal weight. Fetuses were evaluated for externally visible malformations, as well as malformations of the internal organs and skeleton. In the post-partum phase pup mortalities, body weights and litter size as well as incidence of external and gross visceral and skeletal defects were monitored until weaning day 21. The resulting data were compared to the control group. In summary, NaC12-15AE3S induced maternal toxicity, indicated by body weight

changes and other clinical and behavioral observations, when administered by gavage to pregnant rats at doses of 750 mg/kg. The authors were unable to detect any specific abnormality which would indicate a developmental toxicity or teratogenic response related to the treatment. This study was not conducted according to any recognized guideline. However, the study was conducted according to GLP, is well-documented and judged to be scientifically acceptable. Based on the available information the NOAEL for maternal toxicity was estimated to be 375 mg/kg bw/day and the NOAEL for teratogenic effects or developmental toxicity is greater than 750 mg/kg bw/day.

- NH4C13-15AE3S was administered orally by gavage to pregnant Colworth-Wistar rats at dose levels of 0, 63, 125, 250 and 500 mg/kg/day once daily from day 6 to 15 of gestation. Fifteen (15) animals were used per dose group, 10 for dissection and 5 for natural parturition. No detailed information was available on the study design. Some slight maternal toxicity indicated by body weight changes and other clinical observations (e.g. diarrhoea, respiratory wheeziness) was seen in rats with exposure to 250 and 500 mg/kg bw/day, but given the limited information available, there is some uncertainty regarding the severity of these effects. No evidence of developmental toxicity or a teratogenic response to the treatment were reported at any dose level. This study was not conducted according to GLP or according to any recognized guideline. Given the lack of information and the uncertainty mentioned before, a NOAEL could not be reliably determined.
- NaC12-14AE3S was administered orally by gavage to pregnant Colworth-Wistar rats at dose levels of 0, 93, 187, 375 and 750 mg/kg/day once daily from day 6 to 15 of gestation. Fifteen (15) animals were used per dose group, 10 for dissection and 5 for natural parturition. Maternal and foetus effects were evaluated as described previously (i.e study with NaC12-15AE3S). The treatment of pregnant rats with NaC12-14AE3S during days 6-15 of gestation did induce some maternal toxicity at the dose level of 750 mg/kg bw/day. No evidence of treatment-related teratogenic effects or developmental toxicity was reported. This study was not conducted according to GLP or according to any recognized guideline. However, the study appeared well-conducted, was well-documented and judged to be scientifically acceptable. Based on the available information the NOAEL for maternal toxicity was determined to be 375 mg/kg bw/day and the NOAEL for teratogenic or developmental effects is estimated to be greater than 750 mg/kg bw/day.
- NaC16-18AE4S was administered orally by gavage to pregnant Colworth-Wistar rats at dose levels of 0, 63, 125, 250 and 500 mg/kg/day once daily from day 6 to 15 of gestation. Twenty (20) animals were used per dose group, 15 for dissection and 5 for natural parturition. Forty (40) animals were used for the negative control. Maternal, foetus and post-partum effects were evaluated as described previously (i.e study with NaC12- 15AE3S). In summary, there was no evidence of teratogenic potential or developmental toxicity. This study was not conducted according to any recognized guideline. The study was conducted according to GLP, is well-documented and judged to be scientifically acceptable. Based on the available information, the NOAEL for both maternal toxicity, teratogenic and developmental effects appeared to be greater than 500 mg/kg bw/day.
- In a last study of this series, NaC12-15E3S was administered orally by gavage to pregnant Colworth-Wistar rats at dose levels of 0, 125, 250, 500 and 1000 mg/kg/day once daily from day 6 to 15 of gestation. Fifteen (15) animals were used per dose group, 10 for dissection and 5 for natural parturition. Maternal, foetus and post-partum effects were evaluated as described previously. The authors of the

study concluded that a degree of maternal toxicity indicated by a significant reduction in body weight gain of NaC12-15E3S was observed at the highest dose level of 1000 mg/kg. However, no evidence of treatment related developmental toxicity or teratogenic effects was detected. This study was not conducted in compliance with GLP or according to any recognized guideline. The study appeared well-conducted, was well-documented and judged to be scientifically acceptable.

- Pregnant rats were administered 50, 100, and 500 mg/kg/day of C12-13AES by oral gavage on days 6-15 of gestation. Effects observed were a decrease in maternal body weight gain and food consumption. There were no treatment-related maternal effects noted at necropsy or following a uterine examination on day 13 of gestation. The incidence of foetal malformations in AES-treated groups was not different from the control group.
- Several investigators have studied the effects of administering a commercial liquid detergent formulation containing both AES and LAS to pregnant mice, rats and rabbits. Except at dosage levels which were toxic to the dams, no significant differences in the litter parameters of laboratory animals compared to control values were noted in these studies. Levels up to 300 mg/kg of a mixture containing 55% TE3S and 45% LAS given orally to rabbits on days 2-16 of gestation up to 800 mg/kg given to rats on days 6-15 of gestation gave no indications of any embryotoxic or teratogenic effects attributable to AES.

- Estimated Data: none

Endocrine Activity (E): DG

Sodium laureth sulfate was assigned a DATA GAP for Endocrine Activity based on lack of adequate studies. Endocrine activity data was reviewed for other alcohol ethoxysulfates; however, no data was located for any of these compounds.

Data

- Lists
  - *Authoritative:* not included on any screening lists
  - *Screening:* not included on any screening lists

- Measured Data – No data available.

- Estimated Data: none

GROUP II AND II* HUMAN HEALTH EFFECTS (GROUP II AND II* HUMAN)

Note: Group II and Group II endpoints are distinguished in the v1.4 Benchmark system (the asterisk indicates repeated exposure). For Systemic Toxicity and Neurotoxicity, Group II and II* are considered sub-endpoints. See GreenScreen Guidance v1.4, Annex 2 for more details.*

Acute Mammalian Toxicity (AT): L

Sodium laureth sulfate was assigned a hazard classification level of Low with high confidence for acute mammalian toxicity based on oral and dermal LD50 values > 2,000 mg/kg and inhalation LC50s >5mg/L. In addition, acute mammalian toxicity studies in high quality analogs (substances belonging to the alcohol ethoxysulfates category) have confirmed the low acute toxicity. The low hazard conclusion is based on study data specific to the chemical and therefore is reported with high confidence.

Data

- Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists

- Measured Data

  ECHA 2019
  - Rat OECD Guideline 401 (Acute Oral Toxicity) LD50 4,100 mg/kg bw
  - Rat: read-across based on grouping of substances. OECD Guideline 401 (Acute Oral Toxicity) LD50 2000 mg/kg bw

  HERA 2003
  - The acute oral toxicity of alcohol ethoxysulphates (AES) was evaluated with rats in several acute oral toxicity studies. The test materials were typically AES solutions containing 25 – 70% active material. The dilutions were administered at doses ranging from 2.5 – 10 ml/kg bodyweight. Most of the studies predate Good Laboratory Practice (GLP) regulations and in only one of these, the study design included at least 5 animals of each sex per dose group, thus meeting the critical aspect of current testing standards as defined in OECD methodologies. In these studies, the LD50 was estimated to be > 1.3 g active material per kg bodyweight. In a review for the Soap and Detergent Industry Association, Arthur D. Little reported rat oral LD50 values ranging from 1.7 - > 5 g/kg bodyweight
  - A recent study which was rated as reliable without restrictions according to the Klimisch criteria, followed the guidelines of OECD method 401 and was compliant with GLP, a group of ten rats, five of each sex, was given a single oral dose of the triisopranolammonium salt of C12-14AE2S (90% active material) at a dose level of 2000 mg/kg bodyweight. The undiluted liquid was administered by gavage with an application volume of 2 ml/kg bodyweight. The rats were observed daily for any mortalities and clinical symptoms following treatment. Individual body weights were recorded on days 0 (prior to dosing), 7 and 14. At the end of the 14-day observation period, the animals were sacrificed and macroscopically examined. There were no deaths following a single oral application of the tested AES. In conclusion, the acute lethal oral dose to male and female rats of the tested AES was found to be > 2 g/kg.

- In a further study, rated as reliable with restrictions according to the Klimisch criteria, was also conducted according to the guidelines of OECD method 401, but not following GLP standards, a 70% solution of NaC12-14AE2S was administered by oral gavage at a dose level of 2.5 g/kg. No mortalities occurred under the dosing conditions.
- There are no test data available to evaluate the acute inhalation toxicity of AES. Only one study was identified in the review conducted by Arthur D. Little. In this study, rats (group size not specified) survived a 1-hour exposure to 60 mg/l of 59% active material solution of NH4 C12-14AE3S. No additional details are available.
- The acute dermal toxicity of AES has been evaluated in several rat studies and in one rabbit study. Most of the studies did not follow OECD guidelines (e.g. use of small group sizes) and did not comply with GLP regulations. However, despite some protocol deficiencies, the studies were reported in sufficient detail to allow a reasonable assessment of the potential dermal toxicity of AES in laboratory animals. The investigations included mortality and clinical observations. No mortality was observed in the rat studies at the dose level tested and subsequently LD50 values were expressed to be above the highest investigated dose levels, i.e., >0.65 g/kg, >1.12 g/kg, >2.4 g/kg, >1.25 g/kg, >1.08 g/kg, >0.54 g/kg, >1.8 g/kg and 4.6 g/kg.
- Arthur D. Little, 1991 reported dermal LD50 values for AES on both intact and abraded rabbit skin ranging from 4 – 12 g/kg bodyweight.
- An acute dermal toxicity study (limit test) following OECD method 402 and complying with GLP guidelines was performed to assess the acute dermal toxicity of triisopranolammonium salt of C12-14AE2S (90% active material) in the rat. A group of ten rats, five of each sex, was given a single dermal application of the test substance at a dose level of 2 g/kg bodyweight. There were no deaths and no signs of systemic reaction to the treatment.
- The acute lethal dermal dose to male and female rats of NH4C12-14AE2S was determined to be > 2 g/kg bodyweight.

NICNAS 2004

- Sodium Laureth Sulfate:The acute oral toxicity (LD50) in albino rats was 3.2 or 3.38 gives a value of > 2.9 g/kg.
- In one study with Wistar rats 3/10 rats died at a dosage of 1.25 mL/kg.
- Ammonium laureth sulfate: Although in one study the LD50 was < 0.63 mL/kg and 7/10 albino rats died, two larger studies were done with 50 Sprague-Dawley rats and doses of 1 – 100 g/kg of a test solution of either 26 or 27% concentration. Less than 50% of the rats died (5/50 and 12/50) and the LD50s were accordingly calculated at 1.7 or 3.25 g/kg. At dosage levels of 12.1 – 14 g/kg, all animals that died showed reddened lungs, livers, stomachs, intestines and kidneys.
- A single study in rabbits using ammonium laureth sulfate was at a dosage of 0.01 g/kg, with no mortality.

- Estimated Data: none

Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST-single) L

Sodium laureth sulfate was assigned a hazard classification level of low with high confidence for single dose systemic toxicity/organ effects based and no indication of specific target organ toxicity reported following oral or dermal exposures. In addition, acute studies in high quality analogs (substances belonging to the alcohol ethoxysulfate

category) have confirmed the low hazard associated with single dose systemic toxicity/organ effects. While some mild clinical symptoms are reported as a reaction to exposure to this class of chemicals, these effects are determined to be not of toxicological significance (no evidence of toxicity following macroscopic examination) and were only observed to occur at very high concentrations. The low hazard conclusion is based on study data specific to the chemical and therefore is reported with high confidence.

Data

- Lists
  - *Authoritative:* not included on any authoritative lists
  - *Screening:* not included on any screening lists

- Measured Data
- HERA 2003
  - A recent study which was rated as reliable without restrictions according to the Klimisch criteria, followed the guidelines of OECD method 401 and was compliant with GLP, a group of ten rats, five of each sex, was given a single oral dose of the triisopranolammonium salt of C12-14AE2S (90% active material) at a dose level of 2000 mg/kg bodyweight. The undiluted liquid was administered by gavage with an application volume of 2 ml/kg bodyweight. The rats were observed daily for any mortalities and clinical symptoms following treatment. Individual body weights were recorded on days 0 (prior to dosing), 7 and 14. At the end of the 14-day observation period, the animals were sacrificed and macroscopically examined. There were no deaths following a single oral application of the tested AES. The animals showed mild clinical symptoms such as increased activity and piloerection as a reaction to the treatment for approximately four hours after dosing. The macroscopic examination on day 14 showed no significant lesions.
  - In a further study, rated as reliable with restrictions according to the Klimisch criteria, was also conducted according to the guidelines of OECD method 401, but not following GLP standards, a 70% solution of NaC12-14AE2S was administered by oral gavage at a dose level of 2.5 g/kg. No mortalities occurred under the dosing conditions. The rats achieved acceptable bodyweight gains throughout the study and showed mild clinical signs (unkempt fur, abdominal position, diarrhoea) as a reaction to the treatment for approximately 2 hours after dosing. The macroscopic examination on day 14 showed no significant lesions.
  - Arthur D. Little, 1991 reported dermal LD50 values for AES on both intact and abraded rabbit skin ranging from 4 – 12 g/kg bodyweight. At highest dosage levels, various degrees of skin irritation (moderate to severe erythema and oedema) were reported and signs of intoxication included sporadic signs of haemorrhage around the eyes and nose, piloerection, and diarrhoea.
  - An acute dermal toxicity study (limit test) following OECD method 402 and complying with GLP guidelines was performed to assess the acute dermal toxicity of triisopranolammonium salt of C12-14AE2S (90% active material) in the rat. A group of ten rats, five of each sex, was given a single dermal application of the test substance at a dose level of 2 g/kg bodyweight. There were no deaths and no signs of systemic reaction to the treatment. Following removal of the dressing, moderate to severe dermal irritations indicated by inflammation of the epidermis and eschar formation were observed at the treatment site. The effects cleared over time. Some

minor residual skin lesions were observed in 1 animal at the end of the 14-day observation period. No abnormalities were recorded at the macroscopic examination on day 14.

- Estimated Data: none

Systemic Toxicity/Organ Effects incl. Immunotoxicity (ST-repeat) (Group II*) L

Sodium laureth sulfate was assigned a low hazard classification level with high confidence for Repeat Dose Systemic Toxicity/Organ Effects incl. Immunotoxicity based on limited effects reported following oral and dermal exposures. Specifically, no significant toxicity was observed following rat oral exposures at concentrations <100 mg/kg. The organ mostly affected in these studies was the liver, expressed by increased liver weight at high doses, hepatic hypertrophy and occasionally changes in biochemical parameters such as increase of enzyme levels in plasma, generally at levels higher than 250 mg/kg bw/day. These increases, however, were unaccompanied by histological changes and are considered an adaptive nature rather than a toxic effect of the test article. The hazard score is based on study data and supported by studies in high quality analogs and therefore is reported as high confidence.

Data

- Lists
  - *Authoritative:* not included on any screening lists
  - *Screening:* not included on any screening lists

- Measured Data

  ECHA 2019
  - OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents). Doses / Concentrations: 0, 25, 75, 225 mg/kg bw. For the systemic toxicity after repeated oral application a NOAEL of greater than 225 mg/kg bw/day can be deduced.

  HERA 2003
  - NaC12-15AE3S was tested at doses of 0%, 0.023%, 0.047%, 0.094%, 0.188%, 0.375%, 0.75%, 1% and 1.5% in a 3-week dietary rat feeding study. Three (3) animals per sex per dose and 6 animals of each sex in the control group were used. In summary, the organ most affected by the feeding of NaC12-15AE3S was the liver. No effects were observed in rats fed at 0.188% dietary level (254 mg/kg/body weight per day) and less. The lowest observed effect level based on hepatocytic hypertrophy was 0.375% which is equivalent to 487 mg/kg body weight per day. Significantly increased organ weights (liver, kidney, brain) were observed in males and females at doses equal (females) or higher (males and females) than the LOEL established for hepatocytic hypertrophy.
  - NH4C12-15E3S was tested at doses of 0%, 0.023%, 0.047%, 0.094%, 0.188%, 0.375%, 0.75%, 1% and 1.5% in a 3-week dietary rat feeding study. Three (3) animals per sex per dose and 6 animals of each sex in the control group were used. In summary, the only organ affected by the feeding of NH4C12-15E3S was the liver. No effects were observed in rats fed at 0.188% dietary level (232 mg/kg/body weight per day) and less. The lowest observed effect level, based on significant increases in plasma alkaline phosphatase activity, was 0.375% which is equivalent to 465 mg/kg

body weight per day. Significantly increased liver weight was observed in males and females at doses higher than the LOEL established for the change in some plasma enzyme levels.

- NaC12-15E3S containing 21.1% ethanol and 1.15% methanol (note: after mixing with the diet and storage for 3-4 days methanol was no longer detectable and more than 98% of remaining ethanol was evaporated) was tested at doses of 0%, 0.023%, 0.047%, 0.094%, 0.188%, 0.375%, 0.75%, 1% and 1.5% in a 3-week dietary rat feeding study. Three (3) animals per sex per dose and 6 animals of each sex in the control group were used. In summary, the organ mostly affected by the feeding of NaC12-15E3S was the liver. No effects were observed in rats fed at 0.094% dietary level (108 mg/kg/body weight per day) and less. The lowest observed effect level, based on significant increases in plasma alkaline phosphatase activity, was 0.188% which is equivalent to 217 mg/kg body weight per day. Significantly increased liver weight was observed in males and females at doses equal (females) or higher (males and females) than the LOEL established for the change in some plasma enzyme levels.
- NH4C13-15E3S was tested at doses of 0%, 0.023%, 0.047%, 0.094%, 0.188%, 0.375%, 0.75%, 1% and 1.5% in a 3-week dietary rat feeding study. Three (3) animals per sex per dose and 6 animals of each sex in the control group were used. In summary, the organ mostly affected by the feeding of NH4C12-15E3S was the liver. No effects were observed in rats fed at 0.375% dietary level (461 mg/kg/body weight per day) and less. The lowest observed effect level, based on hepatocyte hypertrophy, was 0.75% which is equivalent to 857 mg/kg body weight per day. Significantly increased organ weights (liver, brain, testes) were observed in males and females at doses higher than the LOEL established for hepatocytic hypertrophy.
- NaC12-14E3S was tested at doses of 0%, 0.023%, 0.047%, 0.094%, 0.188%, 0.375%, 0.75%, 1% and 1.5% in a 3-week dietary rat feeding study. Three animals per sex per dose and six animals of each sex in the control group were used. In summary, the only organ affected by the feeding of NH4C12-15E3S was the liver. No effects were observed in rats fed at 0.094% dietary level (120 mg/kg/body weight per day) and less. The lowest observed effect level, based on increase in plasma levels of glutamic-pyruvic transaminase and alkaline phosphatase, was 0.188% which is equivalent to 236 mg/kg body weight per day. Significant changes in organ weights (liver, kidney, heart, adrenals) were observed in males and females at doses higher than the LOEL established for changes in plasma enzyme levels.
- NaC16-18E4S was tested at doses of 0%, 0.023%, 0.047%, 0.094%, 0.188%, 0.375%, 0.75%, 1% and 1.5% in a 3-week dietary feeding study. Three (3) animals per sex per dose and 6 animals of each sex in the control group were used. In summary, the organ mostly affected by the feeding of NH4C12-15E3S was the liver. No effects were observed in rats fed at 0.375% dietary level (468 mg/kg/body weight per day) and less. The lowest observed effect level, based on hepatocyte hypertrophy and increases in plasma levels of glutamicpyruvic transaminase, was 0.75% which is equivalent to 969 mg/kg body weight per day. Significant changes in organ weights (liver, kidney, heart) were observed in males and females at doses higher than the LOEL established for changes in plasma enzyme levels.
- NaC12-15E3S was tested at doses of 0%, 0.023%, 0.047%, 0.094%, 0.188%, 0.375%, 0.75%, 1% and 1.5% in a 3-week dietary rat feeding study. Three (3) animals per sex per dose and 6 animals of each sex in the control group were used. In summary, the organ mostly affected by the feeding of NH4C12-15E3S was the liver. No effects were observed in rats fed at 0.375% dietary level (441 mg/kg/body

weight per day) and less. The lowest observed effect level, based on hepatocyte hypertrophy, was 0.75% which is equivalent to 872 mg/kg body weight per day. Significant changes in organ weights (liver, brain, heart, spleen) were observed in males and females at doses higher than the LOEL established for hepatocyte hypertrophy.

- The Unilever studies summarized above were not conducted according to OECD and GLP guidelines. However, the methodology used was similar in many respects to OECD Guideline No. 407.
- In a 28-day oral gavage rat study, a blend of alkyl (C14-18) sulphate and C12-13E6.5S was tested at 30, 100, 300, and 1000 mg/kg/day. This blend caused irritation to the forestomach of the test animals, evidenced as hyperplasia and hyperkeratosis. Histologically, the hyperplasia appeared as a thickening of the non-glandular stomach epithelium at 100, 300, and 1000 mg/kg/day, but not at 30 mg/kg/day. Similar to the 90-day oral gavage study discussed above, the effects observed in forestomach are considered to be local treatment related and concentration dependent irritant effects. Since there is no human equivalent to the rat forestomach, these effects are not considered to be relevant to human health assessment. No further information is available on this study and thus, a NOEL or NOAEL for systemic toxicity could not be established.
- Synthetic NaC12-15AE3S and natural NaC12AE3S were tested in a 90-day rat diet study at dose levels of 0, 40 200, 1000 and 5000ppm active material. Health, behavior, body weight, food intake, hematological and urinary parameters remained within normal limits at all doses. Total serum protein was increased in males in the 5000ppm dose group of NaC12- 15AE3S. Differences in absolute organ weights were observed at 5000ppm only. Both ethoxysulphates increased kidney weight in males. Liver weight was increased at 5000ppm in both sexes by NaC12-15AE3S. Females receiving NaC12AE3S showed increased liver, kidney and heart weights. A large variation was reported in male heart weights in rats receiving 1000ppm of NaC12-15AE3S, but the increase was not considered to be treatment related. No increase in heart weight was reported for males receiving 5000ppm. Similarly, to the study by Butterworth, a NOEL or NOAEL was not established by the authors but based on the available information and taking a conservative approach, the NOAEL could be established at the dose level of 1000ppm. The study was conducted prior to the development of GLP and OECD guidelines. However, the principles and the procedures were similar in various respects to the OECD test guidelines.
- NaC12-15E3S was fed to rats at dietary concentrations of active ingredient of 0, 40, 200, 500, 1000 and 5000ppm in a 90-day oral feeding study. During the study, observations were made on the general health and behavior, body weight and food intake of each rat. At necropsy, major organs were weighed, and specified tissues examined histologically. Terminal blood samples were taken for hematological and clinical chemical examinations. All animals survived until their scheduled necropsy date. The general health and behavior of control and treated rats were similar throughout the study. No significant change was found in female body weights. Male body weights were significantly higher than controls at 500ppm from week 10 onwards and at 200ppm at weeks 11 and 13. At higher concentrations, there was no difference in body weights from the control values. Male and female liver weights significantly increased at 5000ppm. Absolute testes weights were increased at 5000ppm. However, no differences were observed when adjusted for terminal body weight. These increases were not accompanied by histological, clinical chemical or hematological changes and were therefore considered to be adaptive in nature and

not a toxic effect of the compound. A NOEL or NOAEL was not indicated by the authors but based on the available information and taking a conservative approach, the NOAEL is considered to be 1000ppm. It was not indicated in the report whether the study followed the principles of the OECD method 407 and was GLP compliant.

- NaC12-14AE2S was tested for systemic toxicity at repeated doses by oral gavage of 0 (group 1), 25 (group 2), 75 (group 3), and 225 (group 4) mg/kg bodyweight. The compound was administered by gavage over a period of 90 days. Ten (10) male and female rats were used for each dose. Five (5) male and female animals of groups 1, 3, and 4 were observed to determine the reversibility of possible compound-related alterations for 28-days after treatment. Four (4) animals died during the treatment period. The mortality of the animals was, however, considered to be incidental. Three (3) animals died due to experimental procedures such as anesthesia for blood sampling and the fourth animal was sacrificed due to a traumatic fracture of the mandibula. No systemic treatment-related effects were observed in any test group. The mean food and water consumption was not affected, and the total body weight gain showed no deviations in all male and female test groups. Local treatment effects were only seen in the forestomach. The forestomach of the animals of group 4 showed some lesions such as a hyperplasia, submucosal edema and chronic ulceration. In groups 2 and 3, 3 out of 10 animals showed small eosinophilic foci in the stratified epithelium of the forestomach. In conclusion, according to the study described, a daily administration of NaC12-14AE2S revealed no systemic toxicity but local treatment-related concentration dependent irritation to differing degrees in the forestomach in all main test groups 2 – 4. Thus, a NOEL-value was not determined. Since there is no human equivalent to the rat forestomach, these effects are not considered to be relevant to human health assessment. Looking at systemic toxicity, behavioral and clinical abnormalities and other general or specific toxic effects, a no adverse effect level (NOAEL) of 225 mg/kg could be established. The study followed the OECD guideline method 408. GLP compliance was not indicated in the study report.
- No unusual findings regarding systemic toxicity were noted in a 2-year chronic feeding study in rats in which C12 AE3S was given at 0, 0.1 or 0.5% in the diet for 2 years. An occasional tumor (type and incidence unspecified) was found in various groups. The tumors were characterized as “typical” of those commonly found in aged rats and did not appear to be associated with the ingestion of AES. The results of this study suggests that the NOEL for C12AE3S in this 2-year chronic feeding study in rats was greater than 250 mg/kg bw/day. However, the information available is only very limited and thus only a low study reliability score can be assigned.
- In a 2-year study, rats (20/sex/group) were administered C12AE3S in the drinking water at a concentration of 0.1%. At termination, survival, growth, food consumption, body weights, clinical laboratory findings, hematology and urinalyses were all comparable in control and treated animals. The only unusual finding was slight, but consistently higher water consumption by all rats receiving the test compound in their drinking water and a significant difference in the empty cecum to body weight ratio of females. Absolute organ weights were all comparable to controls and no consistent gross or histopathology was found. Generally, pathological findings for controls and treated rats after 2 years were varied and consisted predominantly of incidental findings attributable to advanced age. Various types of benign and malignant tumors were found in both groups. The incidence and types of tumors observed in the treated group was similar to that of control animals. A NOEL greater than 75 mg/kg bw/day (equals a dose of 0.1% in drinking water) can be estimated on

the basis of the available information.

- Subchronic percutaneous toxicity studies were conducted on 2 liquid dishwashing detergents containing anionic surfactant C12-14AES (detergent A: 23%; detergent B: 27%), C12-14 alkyl sulphate (detergent A: 5%; detergent B: 0%), C12-14 alkylamine oxide (detergent A: 3%; detergent B: 5%), ethanol (detergent A: 5%; detergent B: 7%) and water (balance). The detergents were administered dermally to the shaved backs of rabbits (10 animals per group; 5 of each sex) at concentrations of 0, 0.5, 1.0, and 2.5% in distilled water for 6 hr/day, 5 days/week for a total of 65 treatments (91 days). The dose selection was based on the local irritation effects observed in a 14-day pilot study conducted with each detergent. No adverse systemic effects were observed by assessment of hematological parameters or by gross or microscopic tissue examination at concentrations >12.5 mg/kg/day. Transient slight to moderate dermal irritation at the detergent application site was observed with detergent A. Slight to moderate dermal irritation confined to the detergent application site was noted in the detergent was noted in the detergent B study.

NICNAS 2004

- Sodium laureth sulfate: No observed effect levels were 1000 ppm in the diet of rats in a 13-week subchronic study and 5000 ppm in a 2-year study in relation to gross or microscopic effects. In the 13-week study, sodium laureth sulfate was fed to groups of Carnworth Farm “E” rats (12/sex) at 40, 200, 1000 or 5000 ppm. Rats fed 5000 ppm had increased absolute kidney weights in males and absolute heart, liver and kidney weights in females but there were no changes in relative organ weights.
- Ammonium laureth sulfate induced moderate to severe skin inflammation in a repeated dose 28-day dermal study in rabbits when treated for the first time with 200 mg/kg and then 50 mg/kg subsequently.

- Estimated Data: none

Neurotoxicity (N-single) DG

Sodium laureth sulfate was assigned a DATA GAP for Neurotoxicity (N-single) based on lack of adequate studies. Neurotoxicity (N-single) data was reviewed for other alcohol ethoxysulfates, however, no data was located for any of these compounds.

Data

- Lists
  - *Authoritative: not included on any authoritative lists*
  - *Screening: not included on any screening lists*

- Measured Data – no data available
- Estimated Data: none

Neurotoxicity (N-repeated) (Group II*) DG

Sodium laureth sulfate was assigned a DATA GAP for Neurotoxicity (N-repeated) based on lack of adequate studies. Neurotoxicity (N-repeated) data was reviewed for other alcohol ethoxysulfates, however, no data was located for any of these compounds.

Data
- Lists
  - *Authoritative: not included on any authoritative lists*
  - *Screening: not included on any screening lists*

- Measured Data– no data available

- Estimated Data: none

Skin Sensitization (SnS) (Group II*) L

Sodium laureth sulfate was assigned a low hazard score with high confidence for skin sensitization based on a weight of evidence approach and considering quality criteria (i.e., compliance with OECD methods, GLP) in evaluating reliability of individual studies in numerous alcohol ethoxysulfates including studies specific to sodium laureth sulfate. The vast majority of available guinea pig studies in which AES was tested for skin sensitization properties demonstrated the absence of skin sensitizing potential of AES. Only a few studies indicated a weak sensitization potential of AES, but it should be taken into consideration that observed reactions may have been confounded with irritation reactions. The hazard score is based on guideline study data and therefore is reported as high confidence.

Data
- Lists
  - *Authoritative: not included on any authoritative lists*
  - *Screening: not included on any screening lists*

- Measured Data

  HERA 2003
  - The skin sensitization potential of AES was evaluated in the guinea pig maximization test according the Magnusson-Kligman protocol and in the non-adjuvant Buehler protocol in guinea pigs. Further results of skin sensitization studies are listed in a review conducted for the US soap and detergent industry]. In summary, of 15 studies conducted on different AES batches and materials according to the Magnusson-Kligman protocol, 14 studies revealed no evidence for skin sensitization potential of AES and only 1 study resulted in a positive result, indicating weak sensitization potential of a tested AES batch. Of the available 8 Buehler studies, 6 studies did not indicate any skin sensitization potential of the tested AES batches and 2 studies resulted in a weak positive response. It must be noted that the majority of the available studies were not conducted according to the OECD guideline protocols, nor according GLP standards. Nevertheless, based on the limited information available, these studies appear to be scientifically well conducted and the results should be included in the overall evaluation.
  - NaC12-14AE2S (28% active material) was evaluated in the Magnusson-Kligman guinea pig maximization test according to OECD method 406. In the induction phase, the treatment group was injected on day zero 3 pairs of 0.1ml volume (injection 1: a 1:1 mixture Freunds' complete adjuvant (FCA) and water; injection 2:

0.1% test substance in water; injection 3: 0.1% test substance in a 1:1 mixture FCA) in the shoulder region of female guinea pigs. A week later, a patch containing 30% solution of the test substance was placed over the injection area for 48 hours in the treatment group. The control groups were treated in the same manner, but without the test substance (i.e., 3 injections on day 0 and patch application on day 7). Two weeks after the induction phase, the flanks of the treated and the control animals were cleared of hair and an occlusive 'challenge' patch containing 10% of the test substance (or water in case of the control group) was applied to one flank of the animals for 24 hours. Approximately 48 and 72 hours from the start of the challenge application, the skin reaction was observed and recorded according to the Magnusson-Kligman grading scale. Under the test conditions, NaC12-14AE2S did not cause skin sensitization in guinea pigs.

- Further AES materials such as NaC12-14AE2S (27% active material) and a mixture of sodium laureth sulphate, sodium laureth-8 sulphate and sodium oleth sulphate (5-10EO, 29% active matter) were evaluated according the same protocol and were found to not cause skin sensitization in guinea pigs.
- One batch of NaC12-15E3S caused a weak skin sensitization response. In this study, 20 animals were induced intradermally with a 0.25% aqueous solution of the test item and complete Freund' adjuvant. One week after, an occluded patch containing 50% solution of the test substance was placed over the injection area for 48 hours. After a 14 day rest period, the test animals were challenged with an occluded patch containing a 20% solution of the test substance. 24 and 48 hours after removal of the challenge patch, dermal reactions (score 1) were seen in seven animals. A rechallenge was performed seven days later by applying a 10% aqueous solution of the test substance on the flanks opposite to the treatment area. Two out of twenty animals displayed weak skin effects (score 1).
- In a more recent study, the triisopranolammonium salt of C12-14AE2S was tested according the Buehler method in guinea pigs following OECD guidelines 406 and in compliance with GLP standards. To determine the potential sensitizing effect of this test substance, 20 test animals and 10 control animals were tested with the highest readily tolerated concentration of the test substance, which led to slight to well-defined signs of irritation. A 50% strength formulation was used for treatment during induction phases I, II, and III and a 25% strength formulation of the test substance was administered as the highest non-irritant concentration during challenge. The challenge treatment did not cause any cutaneous reactions in the form of erythema or oedema on the posterior right flank of any treated animal in the test and control groups 30 and 54 hours after administration. Based on these results, the test material NH4C12-14E2S showed no sensitizing effect on guinea pigs under the described test conditions.
- In 1966, skin sensitization associated with exposure to ethoxysulphates was reported in Norway.Walker et al., 1973 conducted a series of investigations to determine the source of this response and identified a contaminant in one particular AES batch shown to be the responsible sensitizing agent. Connor et al., 1975 identified the contaminant in AES to be 1- dodecene-1,3-sultone, 1-tetradecene-1,3 sultone, 2-chloro-1,3 dodecene sultone and 2-chloro1,3-tetradecene sultone. Connor et al. demonstrated that these sultones could be formed only under very specific, extreme AES manufacturing conditions. It became evident that the unsaturated and the chloro-sultones which are considered to be potent skin sensitizers were the result of conditions not normally present and readily avoidable in AES manufacture. The formation of sultones in the AES production is to date not an issue anymore.

Presently, residual levels of unsaturated and chloro-sultones and their precursors are monitored in AES batches on a routine basis.

- Estimated Data: none

Respiratory Sensitization (SnR) (Group II*) DG

Sodium laureth sulfate was assigned a DATA GAP for respiratory sensitization based on lack of adequate studies. Respiratory sensitization data were reviewed for other alcohol ethoxysulfates; however, no data were located for any of these compounds.

Data
- Lists
  - *Authoritative: not included on any authoritative lists*
  - *Screening: not included on any screening lists*

- Measured Data: none
- Estimated Data: none

Skin Irritation/Corrosivity (IrS) H

Sodium laureth sulfate was assigned a high hazard score with high confidence for skin irritation/corrosivity based on a severe irritation that persists to the end of a 14-day observation period following single dermal applications of concentrated forms of alcohol ethoxysulfates. The irritation potential of alcohol ethoxysulfates however, is concentration dependent. Materials with concentrations higher than 70% are moderately to severely irritating to rabbit skin, concentrations between 10 and 30% exhibit mild to moderate irritancy under the conditions of an occluded patch test. AES concentrations below 1% are virtually non-irritating. The hazard score is based on results from a guideline study and are supported by additional results reported for high quality analogs and therefore is reported as high confidence.

Data
- Lists
  - *Authoritative: not included on any authoritative lists*
  - *Screening:*
    - *New Zealand - GHS - 6.3A - Irritating to the skin (Cat. 2)*
    - *EU - Manufacturer REACH hazard submissions - H315 - Causes skin irritation (unverified)*

- Measured Data
  HERA 2003
  - Several skin irritation studies were conducted on rabbits considering different concentrations (0.1%, 1%, 10%, neat material), exposure duration (4h, 24h, 36 h) and exposure conditions (open application, semi-occlusion, full occlusion).
  - The triisopranolammonium salt of C12-14AE2S (90% active material) was tested in an EC standard (4h) skin irritation study on rabbits. The study followed OECD method 404 and was in compliance with GLP regulations. In this study, the undiluted liquid test substance was applied in a single dose for 4 hours to the shorn intact skin

of three animals. The administration of the test substance led to well-defined erythema 24 hours after application and was associated with distinct oedema in two animals and severe oedema in the 3rd animal. Forty– eight (48) hours after application, these signs of irritation were still well-defined and without change in 2 out of 3 animals. The 3rd animal presented with moderately severe erythema, associated with severe oedema, dry skin and scaling, 48 hours after application. Seventy-two (72) hours after application, 2 animals exhibited localized skin irritation in the form of well-defined or moderately severe erythema and oedema, and 1 rabbit had slight subcutaneous haemorrhages. On the 14th day after administration of the test substance, the skin of all the animals was free from signs of irritation. For all 3 animals, an erythema/eschar mean score of 2.33 and an oedema mean score of 2.78 was determined. This score indicates moderate skin irritation properties of the undiluted test substance.

- In two further studies, NaC12-14AE2 (70% active material) was tested in the EC standard irritation test. Both studies were conducted in compliance with OECD method 404, but only 1 complied with GLP regulations. As in the case of the study discussed before, exposure to the test substance for 4 hours resulted in moderate to severe erythema and oedema. After 72 hours, reduced flexibility, fissuring of the skin and severe erythema and oedema were apparent. One study terminated the observations at the 14th observation day and clinical signs of irritation were still apparent at this time. In the other study, animals were observed for 21 days and irritation had completely resolved within 21 days after exposure, but patches of bold skin persisted at termination.
- Further studies were conducted to investigate the skin irritation of effects of various dilutions of AES at different exposure durations and conditions. These studies were investigative in nature and neither was in compliance with OECD guidelines, nor with GLP regulations. However, these studies provide useful information on AES exposure conditions that are of particular relevance in consumer product applications. In 4hr or 24hr skin irritation studies on rabbits, a 0.1% AES solution did not show any signs of irritation, a 1% AES solution showed slight irritation, and solutions containing AES of 10 – 30% were mildly to moderately irritating under the patch conditions of the animal test.
- The cumulative skin irritation effects of formulations containing AES have been investigated in six separate “24-hour Repeat Application Patch Test” studies. In each study 12 volunteers were treated with patches of a 0.1% (w/v) aqueous solution of detergent formulations containing AES (Na AES CAS# 68585-34-2). The patches were applied on the upper arms, under fully occlusive conditions. Test material was applied for 24 hours, 3 times a week at the same skin site, for a total of one week. After the end of each 24-hour application period, the skin was graded for irritation according to a 0 – 4 scoring scale. A total of 12 different detergent formulations were tested with the following AES concentrations (% w/v): 11, 13, 16, 18, 19, 20. A total of 72 volunteers were tested. All the formulations tested resulted in cumulative average skin irritation scores lower than 0.8 (they ranged between 0.05 and 0.79), which corresponds to a very mild effect.
- In a separate, similar study the cumulative irritancy potential of a detergent formulation containing 11.4% (w/v) AES (Na AES CAS# 68891-38-3) was investigated under open (nonocclusive) conditions. A total of 12 volunteers were treated with 0.3 ml of undiluted, 30% (w/v), and 10% (w/v) aqueous dilutions of the detergent formulation, which were applied on an open application patch on the upper arms. Test materials were applied for 24 hours, 3 times a week at the same skin site,

for a total of one week. After the end of each 24 hour application period, the skin was graded for irritation according to a 0 – 4 scoring scale. The cumulative average scores for the undiluted, 30%, and 10% detergent formulation were 0.26, 0.03, and 0.03, respectively. These scores are all indicative of a very mild effect.

NICNAS 2004

- Sodium laureth sulfate: A large number of studies were performed with a variety of concentrations under occlusive patch for 24 – 48 hours. Applications produced no irritation at 5 – 5.6%, mild erythema and oedema at 6 – 10%, 17.5% and 26%. Severe irritation occurred at 15, 25, 28 and 30%. Severe irritation was produced in 3 applications of a 15% solution on consecutive days but similar studies with 17.5% produced only mild irritation. Single applications of 26 and 28% produced mild and moderate irritation, respectively, and an application of 58% produced no irritation. Three studies using 30% applications for 3 days produced severe irritation. Effects on the skin and hair cycles were investigated by application of the chemical daily for 65 days. A 60% concentration caused inflammatory changes, epidermal hyperplasia, epidermoid cyst formation and diffuse hair loss. A 30% concentration caused similar but less severe changes and 9% caused no changes.
- Ammonium laureth sulfate: A large number of studies on albino rabbits suggested that 7.5% was slightly irritating, 12 – 15% moderately irritating and 25 – 60% severely irritating.
- An 18% solution of sodium laureth sulfate produced a low level of irritation in 3 of 20 subjects but a second 18% solution induced mild irritation in 11 of 20 subjects when applied under a 24-hour occlusive patch.
- A 21-day subchronic dermal study showed a 1.25% solution to be highly irritating while another study utilising a 0.07% solution indicated a moderate potential for mild cumulative irritation in the four subjects who completed the study.
- Ammonium laureth sulfate: Irritant contact dermatitis was produced during a standard repeated insult patch test using 0.29% for induction and 0.15% for challenge. During induction, one third of subjects had mild to moderate irritation. A similar conclusion was reached when 0.115% was tested in a formulation, and also 0.23%.

- Estimated Data: none

Eye Irritation/Corrosivity (IrE): *vH*

Sodium laureth sulfate was assigned a very high hazard score with low confidence for eye irritation/corrosivity based on studies moderately to severely irritating to rabbit eyes. Specifically, ocular findings indicate a concentration dependence on the severity of eye damage with many studies reporting effects observed throughout a 21-day observation period. Unless data are available that show absence of the irritating potential as defined by the EC criteria the classification Xi, R41 according to Directive 67/548/EEC and Eye Dam. 1, H318 according to Regulation (EC) 1272/2008 will be applied for the neat substance. Therefore, based on professional judgement it is determined that sodium laureth sulfate fulfils a GHS Category 1A eye irritant. As professional judgement was used in assigning a very high hazard score, the score is reported with low confidence.

Data

- Lists

- *Authoritative: not included on any authoritative lists*
- *Screening:*

  New Zealand - GHS - 8.3A - Corrosive to ocular tissue (Cat. 1)
  EU - Manufacturer REACH hazard submissions - H318 - Causes serious eye damage (unverified)
  EU - Manufacturer REACH hazard submissions - H319 - Causes serious eye irritation (unverified)

- Measured Data

  NICNAS 2004
  - Sodium laureth sulfate: Eye irritation in albino rabbits using 1.3 – 58% ranged from no irritation to severe eye damage with no dose dependency.
  - Ammonium laureth sulfate: A concentration of 7.5% produced slight irritation rising to severe irritation in a dose-dependent manner at 60%.

  HERA 2003
  - The potential of AES to cause eye irritation under accidental exposure conditions has been evaluated in several rabbit eye irritation studies. Most of the studies with undiluted or concentrated AES solutions (e.g. 32.6% C9-11AE2.5S, 70% C12-13AE2S, 28% C12-13AE2S) resulted in extensive corneal damage, inflammation of the iris and maximal conjunctival irritation with no significant improvement seen over a 7-day recovery period after product administration. In the same studies, which were neither conducted according to OECD guidelines (e.g., protocol deviations such as application volume and observation period), nor followed the principles of GLP, the authors also investigated the same materials at concentrations of 10%, 1% and 0.1%. Generally, solutions containing 10% AES were observed to cause moderately irritating effects while 1% and 0.1% dilutions were virtually non-irritating. The most reliable studies will be discussed in the following paragraph in more detail.
  - The triisopranolammonium salt of C12-14AE2S (90% active material) was tested in an acute eye irritation study (“Draize test”) according to OECD method 405 and following the principles of GLP. In this study, 0.1ml of the liquid test substance was administered into the conjunctival sac of one eye of each of the 3 rabbits. After an exposure time of 24 hours, the eyes were flushed with warm physiological saline. Twenty-four hours after exposure, the animals were observed to have reactions of the conjunctivae in the form of diffuse crimson red discoloration (individual blood vessels not easily discernible), together with distinct swelling and partial eversion of the eyelids. The cornea was slightly opaque over the entire surface, and the iris of one animal showed severe hyperaemia. Up to 72 hours after administration, these signs of irritation were largely unchanged and after 6 days, all signs of irritation began to diminish. After day 17, 2 animals were free from signs of irritation of the eye and mucosa. The 3rd animal was cleared after 24 days.
  - In another study, 28% active C12-14AE2S was also tested in the Draize test, following the guidelines specified in the OECD method 405. GLP compliance was not mentioned. Again, in this study the tested AES material caused corneal opacity, iritis and conjunctivitis in all test animals. While the conjunctivitis appeared to improve in all 3 test animals approximately 8- 10 days after exposure to the test material, corneal opacity and the circumcorneal injection in the iris were still present in 2 animals after 21 days.
  - Further investigative studies were conducted to determine the effect of rinsing and AES alkyl chain length on the eye irritation potential in rabbits. It was found that rinsing after instillation greatly reduced the severity of eye effects and that AES in

the C12-16 range produced more severe effects than AES with longer or shorter chains. This was primarily manifested by longer clearing times (> 7 days versus 1-7 days).

- Estimated Data: none

ECOTOXICITY (ECOTOX)

Acute Aquatic Toxicity (AA): H

Sodium laureth sulfate was assigned a high hazard score with high confidence for acute aquatic toxicity based on LC50 and EC50 values between 1-10 mg/L reported for fish, invertebrates and algae. The hazard score is based on results from guideline studies and therefore is reported as high confidence.

Data

- Lists
  - *Authoritative: not included on any authoritative lists*
  - *Screening: not included on any screening lists*

- Measured Data
  ECHA 2019
  - In one of the tests zebrafish (*Danio rerio*) were exposed to different concentrations of alcohol C12 -14 ethoxysulfates (2EO) (CAS 68891 -38 -3; purity of the test substance. 71.5% a.s.) in a flow-through system. The study was conducted according to the guidelines OECD 203 and EG Guideline 92/69 C.1 under GLP-conditions. The resulting LC50 (96 h)-value is reported to be 7.1 mg a.s./L (Scholz, Sasol, 1994). This study is defined as key study.
  - One study on daphnids is available for AES (C12-14, 1-2.5EO) Na (CAS 68891-38-3) (Scholz, Sasol, 1993). In that study Daphnia magna were exposed to different concentrations of alcohol C12 -14 ethoxysulfates (2EO) (CAS 68891 -38 -3; purity of the test substance: 71.5% a.s. and 69.7% a-WAS) in a static system according to the guidelines OECD 202 and EG Guideline 92/69/EWG under GLP-conditions. In that study an EC50 (48 h)-value of 7.2 mg/L based on a-WAS (corresponding to 7.4 mg a.s./L) could be determined.
  - Three algae studies are available for AES (C12-14, 1-2.5EO) Na (CAS 68891-38-3). In one of the tests *Scenedesmus subspicatus* were exposed to different concentrations of alcohol C12 -14 ethoxysulfates (2EO) (CAS 68891 -38 -3; content of active substance in test material: 69.7% a-WAS) in a static system according to the guidelines OECD 201 and EG Guideline 92/69 C.1. The GLP-study resulted in an EC50 (72 h)-value for growth rate of 27 mg/L as a-WAS (corresponding to 27.7 mg a.s./L) (Scholz, Sasol, 1993). In a further GLP-study *Scenedesmus subspicatus* were exposed to different concentrations of C12 -14 alcohol ethoxysulfates according to the guideline DIN 38412, part 8 (Wierich, Cognis, 1993). The test results in an EC50 value of 7.7 mg a.s./L. As in the study of Wierich (Cognis, 1993) a product is tested that contains only 25% of the active substance, the study of Scholz (Sasol, 1993), which reported an EC50 of 27.7 mg a.s./L for growth rate after 72 h of exposure is regarded as key study. In another supporting study, EC50 -values for growth rate for *Scenedesmus subspicatus* were reported to be 2.6 mg a.s./L (Berger and Guhl, 1998). In case of the study of Berger and Guhl (1998) only a short summary is available and thus that study could not fully evaluated.

- Estimated Data: none

Chronic Aquatic Toxicity (CA): H

Sodium laureth sulfate was assigned a high hazard score with high confidence for chronic aquatic toxicity based on a measured NOEC values between 0.1-1 mg/L reported for fish and invertebrates. The hazard score is based on results from guideline studies and therefore is reported as high confidence.

Data

- Lists
  - *Authoritative: not included on any authoritative lists*
  - *Screening:*
    - *EU - Manufacturer REACH hazard submissions - H412 - Harmful to aquatic life with long lasting effects (unverified)*
    - *German FEA - Substances Hazardous to Waters - Class 1 - Low Hazard to Waters*

- Measured Data

  ECHA 2019
  - To assess the long-term toxicity of AES (C12-14, 1-2.5EO) Na (CAS 68891-38-3) one study is available. The results of that key study are supported by investigations with the pure AES homologue (C14, 2EO) Na (CAS 27731-62-0) and with the similar alcohol ethoxysulfate mixture (C14-16, 2EO) Na (CAS 68585-34-2). To determine the toxic effect of the AES (C12-14, 2EO) Na a study similar to OECD guideline 215 was performed (TEGEWA, 1995). In this test juvenile individuals of rainbow trout (*Oncorhynchus mykiss*) were exposed to different concentrations of AES (C12 -14, 2EO) Na under flow-through conditions. Mortality and growth were determined over 28 days. Related to mortality and sublethal effects a NOEC of 0.14 mg/L (measured) was determined.
  - This result is supported by a non-GLP study carried out similar to OECD guideline 210, eggs of fathead minnow (*Pimephales promelas*) were exposed to the pure AES homologue (C14, 2EO) Na (Rawlings, P&G, 2004). Under flow-through conditions a NOEC (28 d) of 0.18 mg/L (measured) was determined. The NOEC based on mortality.
  - Two further studies are available for AES (C14-16, 2EO). In the first study fathead minnow fry were exposed in a flow-through system (Lewis and Hamm, P&G, 1979a). In the second study fathead minnow juveniles were exposed in the same way with the same mixture (Lewis and Hamm, P&G, 1979b). Both tests were conducted according to OECD 203 over 45 days. In both studies a NOEC for growth (length and weight) was reported to be 1.0 mg/L.
  - One chronic invertebrate study is available for AES (C12-14, 1-2.5EO) Na (CAS 68891-38-3). In that study which is conducted by Makki (P&G, 1977) equivalent to the OECD guideline 211 a NOEC for survival and reproduction was determined to be 0.27 mg/L after 21 days. That reliable study is determined to be the key study. The results of that key study could be confirmed by two reliable tests conducted with comparable mixtures, alcohol C14 -15 ethoxysulfates (Hoberg & Pittinger, P&G, 1987 and Belanger et al., P&G, 1997) resulting in NOEC-values of 0.18 mg/L (after 21 days) and 0.730 mg/L (after 8 weeks). These values are within the same range as the NOEC described by Makki (P&G, 1977). In addition, a further test conducted with alcohol C12 -14 ethoxysulfates available which reports an NOEC-value of 0.72

mg/L (Berger & Guhl, Cognis, 1998). That study could not be fully evaluated as only a short summary is available.

- Estimated Data: none

ENVIRONMENTAL FATE (FATE)

Persistence (P): vL

Sodium laureth sulfate was assigned a very low hazard score with high confidence for persistence based on meeting the readily biodegradable 10-day window in tests conducted under the conditions of OECD Guidelines. The hazard score is based on results from guideline studies and are supported by additional results reported for high quality analogs and therefore is reported as high confidence.

Data

- Lists
  - *Authoritative: not included on any authoritative lists*
  - *Screening: not included on any screening lists*

- Measured Data

  ECHA 2019
  - All members of the category alkyl ether sulfates are readily biodegradable which is proved by several studies available for different mixtures.
  - Several reliable studies on the ready biodegradability of alcohols C12 -14 ethoxysulfates are available. All studies were conducted according or equivalent to OECD or EU-guidelines and under GLP. In all tests the ready biodegradability of the test substance could be proved via determination of DOC-removal or O2 -consumption. Degradation rates of the ready biodegradability studies ranged from 76 - 81% for the parameter O2 -consumption and from 96 - 100% for the parameter DOC-removal.
  - In a high quality GLP-study Biodegradation of 100% based on DOC-removal is reported after 28 days of exposure. The study was conducted according to the EU-method C.4-A.
  - In addition, two further studies are available (Zielinski, PCC-Rokita, 2005 and 2007). Both tests describe the ultimate aerobic biodegradation of the C12 -14 alcohol ethoxysulfate mixtures after 28 days. In both tests the biodegradability was tested using the EEC C4 -D manometric respirometry method. Biodegradability was determined to be 68% or 74 % (COD) and 60% (ThOD). Both tests conclude that the substance meets the criteria for ultimate aerobic biodegradation.

  HERA 2003
  - AE homologues with linear hydrocarbon chain lengths from C8 to C15 and mean values ranging from 3-20 EO units are readily biodegradable. AE homologues with C16 or C18 hydrocarbon chain lengths and mean values between 2 and more than 20 ethylene oxide units are also readily biodegradable. Good quality data (Klimisch score 1) is also available for a 2-butyl substituted oxo-C12EO5 AE homologue, showing more than 60% ThCO2 removal in a 28-day CO2 evolution test (Marcomini et al, 2000b), which indicates that the presence of one short alkyl chain in the 2 position, especially one of 4 carbons or less, will not reduce the ability of the homologue to pass a ready biodegradability test. In conclusion, the available data confirm that the AE homologues used in detergent and household cleaning applications and included in this HERA assessment are readily biodegradable.

  NICNAS 2004

- AES is readily biodegradable under aerobic conditions. Biodegradation is greater for linear primary AES (as is the case here) than for branched tetra-propylene primary AES. In OECD TG 301 tests, rapid primary degradation of 70-100% in 1 to 5 days is reported for AES of chain length C12-14. Biodegradation occurs through cleavage of the ether bond, which may take place at any ether bond. Cleavage produces a fatty alcohol or an alcohol ethoxylate, and ethylene glycol sulfates of various lengths (Madsen et al 2001). The alcohol is subsequently degraded by oxidation, whereas the ethylene glycol sulfate is eliminated stepwise by oxidation, cleavage of C2-units, and desulfation.
- AES is readily biodegraded under anaerobic conditions, with tests showing 64% removal in 28 days for C12-14 chain lengths. In ultimate anaerobic tests with digester sludge (24-29 g/L medium), 88% was degraded after 17 days incubation at 35°C. Anaerobic biodegradation pathways have not been verified.

- Estimated Data: none

Bioaccumulation (B): *vL*

Sodium laureth sulfate was assigned a very low hazard score with low confidence for bioaccumulation based on a reported log K_{ow} of <4. This very low bioaccumulation potential is supported by whole body BCF values reported in fish of 18 and 4.7 for C12 AE3S and C12AE5S respectively. The hazard score is based on equivocal data that was reported only in a secondary literature source and therefore is reported as lower confidence.

Data

- Lists
  - *Authoritative: not included on any authoritative lists*
  - *Screening: not included on any screening lists*

- Measured Data

  ECHA 2019
  - the study does not need to be conducted because the substance has a low potential for bioaccumulation based on log Kow <=3
  - The partition coefficient log Pow is 0.3 at 23 °C, pH 6.1 (OECD 123).

  NICNAS
  - The uptake, distribution and elimination of 35S labelled C12 AE3S and C12AE5S have been investigated in Carp (*Cyprinus carpio*). The following BCF values for the two substances respectively were determined: Whole body, 18 and 4.7; gall bladder, 3400 and 940; and hepatopancreas, 46 and 18. Both uptake and elimination were reported to be rapid. The high concentrations found in the gall bladder were thought to be due to biotransformation of AES in the liver and subsequent excretion of radiolabelled metabolites in the gall bladder. Due to metabolism in organisms, it was thought that the BCF values were overestimated. For the whole body, and the gall bladder, steady state was not reached within 72 hours, hence the reported values are considered to be invalid. Masden et al (2001) concluded that AES is not considered to bioconcentrate in aquatic organisms.

- Estimated Data: none

PHYSICAL HAZARDS (PHYSICAL)

Reactivity (Rx): *L*

Sodium laureth sulfate was assigned a low hazard score with low confidence for reactivity based on the absence of chemical groups that are associated with explosivity or oxidizing properties. The reactivity endpoints reported for Sodium laureth sulfate are not directly comparable to the hazard breaks within GreenScreen and therefore professional judgement has been used in determining the low hazard score. The hazard score is based on professional judgement using the available data and is reported as low confidence.

Data
- Lists
  - *Authoritative: not included on any authoritative lists*
  - *Screening: not included on any screening lists*

- Measured Data – No data available.

- Estimated Data
  ECHA 2019
  - The available data on explosive properties of the test substance do not meet the criteria for classification according to Regulation (EC) 1272/2008 or Directive 67/548/EEC and are therefore conclusive but not sufficient for classification: based on chemical structure the substance is not explosive.
  - On the basis of the chemical structure the substance is incapable of reacting exothermically with combustible materials.
  - Based on the chemical structure and experience in handling and use, pyrophoricity and flammability on contact with water are not expected.

Flammability (F): L

Sodium laureth sulfate was assigned a low hazard with high confidence for flammability based on results from the EU A.10 test that the substance is non-flammable. The hazard score is based on measured data and is therefore reported as high confidence.

Data
- Lists
  - *Authoritative: not included on any authoritative lists*
  - *Screening: not included on any screening lists*

- Measured Data
  ECHA 2019
  - The substance propagated combustion along 200 mm in the preliminary test only after 40 minutes. Therefore, the burning rate test did not need to be done.
  - Based on the EU A.10 test, the substance is non-flammable.
  - The boiling point is > 400 °C at 101 kPa (ASTM E 737-76).

- Estimated Data: none

REFERENCES

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APPENDIX A: HAZARD CLASSIFICATION ACRONYMS

(alphabetical order)

(AA) Acute Aquatic Toxicity

(AT) Acute Mammalian Toxicity

(B) Bioaccumulation

(C) Carcinogenicity

(CA) Chronic Aquatic Toxicity

(D) Developmental Toxicity

(E) Endocrine Activity

(F) Flammability

(IrE) Eye Irritation/Corrosivity

(IrS) Skin Irritation/Corrosivity

(M) Mutagenicity and Genotoxicity

(N) Neurotoxicity

(P) Persistence

(R) Reproductive Toxicity

(Rx) Reactivity

(SnS) Sensitization- Skin

(SnR) Sensitization- Respiratory

(ST) Systemic/Organ Toxicity

APPENDIX B – MODELING RESULTS

Attach:

- **EPISuite - None**
- **ECOSAR - None**
- **Other - None**

APPENDIX C – PHAROS OUTPUT FOR Alcohols, (C12-14), Ethoxylated, monoehters with sulfuric acid, sodium salts (CAS# 68891-38-3)]

[68891-38-3] ALCOHOLS, (C12-14), ETHOXYLATED, MONOETHERS WITH SULFURIC ACID, SODIUM SALTS

General Information | Hazards | Process Chemistry Research | GreenScreen | C2C | Sources

Direct Hazards:

EYE IRRITATION	New Zealand - GHS - 8.3A - Corrosive to ocular tissue (Cat. 1) EU - Manufacturer REACH hazard submissions - H318 - Causes serious eye damage (unverified) EU - Manufacturer REACH hazard submissions - H319 - Causes serious eye irritation (unverified)	+2
SKIN IRRITATION	New Zealand - GHS - 6.3A - Irritating to the skin (Cat. 2) EU - Manufacturer REACH hazard submissions - H315 - Causes skin irritation (unverified)	+1
CHRON AQUATIC	EU - Manufacturer REACH hazard submissions - H412 - Harmful to aquatic life with long lasting effects (unverified)	
MULTIPLE	German FEA - Substances Hazardous to Waters - Class 1 - Low Hazard to Waters	
POSITIVE LIST	US EPA - DfE SCIL - Green Circle - Verified Low Concern	

APPENDIX D – USE OF THE ASSESSMENT

When making reference to this GreenScreen assessment, users shall include the following note:

> The publicly available, certified GreenScreen Assessment for Sodium Laureth Sulfate (CAS# 68891-38-3) was prepared by WAP Sustainability Consulting, LLC on April 24th, 2019, expiring April 24th, 2024, the details of which can be found at http://www.wapsustainability.com/greenscreen-for-safer-chemicals.

This reference shall be used when the final GreenScreen benchmark score is shown without access to this full assessment report, including, but not limited to, Health Product Declarations (HPDs) and manufacturer's inventories for LEED documentation.