



Calcium and magnesium salts of alkyl aryl sulfonates: Human health tier II assessment

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Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
Benzenesulfonic acid, tetrapropylene-, calcium salt	11117-11-6
Benzenesulfonic acid, dodecyl-, calcium salt	26264-06-2
Benzenesulfonic acid, dodecyl-, magnesium salt	27479-45-4
Benzenesulfonic acid, didodecyl-, calcium salt	29299-35-2
Sulfonic acids, petroleum, calcium salts	61789-86-4
Sulfonic acids, petroleum, magnesium salts	61789-87-5
Benzenesulfonic acid, C10-16-alkyl derivatives, calcium salts	68584-23-6
Benzenesulfonic acid, propenated, calcium salt, overbased	68610-84-4
Sulfonic acids, petroleum, calcium salts, overbased	68783-96-0

Chemical Name in the Inventory	CAS Number
Benzenesulfonic acid, mono-C11-13-branched alkyl derivatives, calcium salts	68953-96-8
Benzenesulfonic acid, propenated, calcium salts	69102-89-2
Benzenesulfonic acid, C16-24-alkyl derivatives	70024-67-8
Benzenesulfonic acid, mono-C16-24-alkyl derivatives, calcium salts	70024-69-0
Benzenesulfonic acid, mono-C16-24-alkyl derivatives, calcium salts, overbased	70024-71-4
Benzenesulfonic acid, mono-C19-28-alkyl derivatives, calcium salts, overbased	70024-72-5
Benzenesulfonic acid, mono-C15-30-branched alkyl and di-C11-13-branched and linear alkyl derivs., calcium salts, overbased	71486-79-8
Benzenesulfonic acid, mono- and dialkyl derivatives, magnesium salts	71786-47-5
Benzenesulfonic acid, polypropenated magnesium salt, overbased	256422-07-8
Benzenesulfonic acid, 4-C10-14-alkyl derivatives, calcium salts	90194-26-6
Benzenesulfonic acid, C10-60-alkyl derivatives, calcium salts	90194-27-7
Benzenesulfonic acid, 2,3(or 3,4)-dimethyl-, mono-C10-14-branched alkyl derivatives, calcium salts	90218-31-8
Benzenesulfonic acid, C10-60-alkyl derivatives, magnesium salts	93028-29-6
Benzenesulfonic acid, mono-C10-13-sec-alkyl derivatives, calcium salts	97467-80-6
Benzenesulfonic acid, C20-30-alkyl derivatives, calcium salts	103213-14-5
Benzenesulfonic acid, C20-30-alkyl derivatives, magnesium salts	103213-15-6

Chemical Name in the Inventory	CAS Number
Benzenesulfonic acid, mono-C20-24-alkyl derivs., calcium salts	156105-31-6

Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit: www.nicnas.gov.au

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ACRONYMS & ABBREVIATIONS

Grouping Rationale

The chemicals in this group are salts of structurally related linear and branched alkylbenzene sulfonates (LAS and BAS) that are anionic surfactants with molecules characterised by a hydrophobic (non-polar) tail and a hydrophilic (polar) head.

All the chemicals in this group consist of a benzene ring with a sulfonic acid substituent group and an alkyl chain that can vary in length and extent of branching. They are manufactured by reacting the parent alkylbenzenes with sulfuric acid or sulfur trioxide to give the corresponding sulfonic acid, which is neutralised with a calcium or magnesium base to form the desired salt (IPCS, 1996). The salts can also be complexed (overbased) with an excess of metal carbonate and for toxicological purposes can be considered as a mixture of the surfactant and the metal carbonate. The overbased products exist in the lubricating oil diluent as a reverse micelle.

The chemicals have similar physicochemical properties, such as low water solubility; low vapour pressure; high viscosity, density and melting points; and relatively high molecular weights. The solubility of the homologues can differ based on the alkyl chain length, usually decreasing with increasing chain length. Although the carbon chain length in this group of chemicals varies, they all are expected to have essentially similar physicochemical properties.

Most of the chemicals in this group have similar end uses, typically in lubricating oils and cleaning products. The salts are expected to dissociate almost completely below the critical micelle concentration. The chemicals in this group are expected to have similar toxicity, which is primarily due to the alkylbenzene sulfonate anion.

Import, Manufacture and Use

Australian

The following Australian industrial uses were reported under previous mandatory and/or voluntary calls for information.

The following chemicals have reported commercial or domestic uses as cleaning agents, surfactants, lubricants or additives:

- sulfonic acids, petroleum, calcium salts (CAS No. 61789-86-4);
- benzenesulfonic acid, C10-16-alkyl derivatives, calcium salts (CAS No. 68584-23-6);
- sulfonic acids, petroleum, calcium salts, overbased (CAS No. 68783-96-0);
- benzenesulfonic acid, C16-24-alkyl derivatives (CAS No. 70024-67-8);
- benzenesulfonic acid, mono-C16-24-alkyl derivatives, calcium salts (CAS No. 70024-69-0); and
- benzenesulfonic acid, mono-C16-24-alkyl derivatives, calcium salts, overbased (CAS No. 70024-71-4).

For the above chemicals, the total volume introduced into Australia, reported under previous mandatory and/or voluntary calls for information, was <1000 tonnes.

International

The following international uses have been identified through the European Union Registration, Evaluation, Authorisation and Restriction of Chemicals (EU REACH) dossiers; the Organisation for Economic Cooperation and Development Screening Information Dataset Initial Assessment Report (OECD SIAR); Galleria Chemica; Substances and Preparations in the Nordic countries (SPIN) database; the European Commission Cosmetic Ingredients and Substances (CosIng) database; United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) dictionary; eChemPortal: OECD High Production Volume chemical program (OECD HPV); the US Environmental Protection Agency's Aggregated Computational Toxicology Resource (ACToR); and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

Benzenesulfonic acid, dodecyl-, calcium salt (CAS No. 26264-06-2) and benzenesulfonic acid, dodecyl-, magnesium salt (CAS No. 27479-45-4) are reported in the CosIng database with the identified cosmetic functions of cleansing and as a surfactant. However, no reported uses were identified in the United States Cosmetic Ingredient Review (CIR) report (2010) or in the Compilation of Ingredients Used in Cosmetics in the United States (Personal Care Products Council, 2011).

The chemicals in this group have reported domestic or commercial use including in:

- paints, lacquers and varnishes;
- as surfactants;
- corrosion inhibitors;
- lubricants and additives;
- as surface treatments; and
- cleaning and washing agents.

The chemicals (CAS Nos. 26264-06-2, 27479-45-4, 61789-86-4 and 71486-79-8) are reported to be present in a range of domestic products (including auto cleaning and dishwashing products) up to concentrations of 4 % (Household Products Database, US Department of Health and Human services).

The chemicals in this group have reported commercial use including in:

- fuel additives;
- antifreezing agents;
- cutting fluids;
- fertilisers; and
- hydraulic fluids and additives.

Benzenesulfonic acid, dodecyl-, calcium salt (CAS No. 26264-06-2 and C10–16 alkylbenzenesulfonic acid (CAS No. 68584-22-5) have reported non-industrial use in preservatives and agricultural pesticides.

Most of the chemicals in this group are produced internationally at high volumes (100–1000 tonnes/year):

- CAS Nos. 61789-86-4, 68610-84-4, 68783-96-0, 70024-67-8, 70024-72-5, 90194-26-6, 93028-29-6 and 11117-11-6 are on the OECD list of high production (HPV) volume chemicals (>1000 tonnes) (OECD, 2009);
- CAS Nos. 26264-06-2, 61789-86-4, 61789-87-5, 68783-96-0, 68953-96-8, 70024-67-8, 70024-69-0, 71486-79-8 and 71786-47-5) are on the US EPA High Production Volume Program Chemical List (500 tonnes/year) (Galleria Chemica); and
- CAS Nos. 61789-87-5 and 68610-84-4 have a reported annual production of 100–1000 tonnes in the EU and the US (REACHg; REACHi).

Restrictions

Australian

No known restrictions have been identified.

International

Benzenesulfonic acid, dodecyl-, calcium salt (CAS No. 26264-06-2) and benzenesulfonic acid, dodecyl-, magnesium salt (CAS No. 27479-45-4) are listed in the US CIR as safe in the present practices of use and concentration when formulated to be non-irritating.

Existing Worker Health and Safety Controls

Hazard Classification

The chemicals in this group are not listed on the Hazardous Chemicals Information System (HCIS) (Safe Work Australia).

Exposure Standards

Australian

No specific exposure standards are available.

International

Most of the chemicals in this group have international exposure standards (Belarus, Estonia, Germany, US Idaho and/or US Oregon) ranging from 2–10 mg/m³ as respirable dust or total dust (Galleria Chemica).

Health Hazard Information

The chemicals are expected to exist almost entirely as the linear or branched alkylbenzenesulfonate (LAS/BAS) anions at the pH of biological solutions. The cation components of the chemicals (calcium and magnesium) are not expected to contribute significantly to the toxicity of the chemicals. Where limited or no data were available for the chemicals, data from linear alkylbenzene sulfonic acids (LASA) and other LAS and BAS were used as read across.

Toxicokinetics

The toxicokinetic properties for the calcium and magnesium salts of LAS in this group are expected to be similar to the sodium salts of LAS. The chemicals are readily absorbed through the gastrointestinal (GI) tract, are distributed throughout the body and are extensively metabolised. The parent compound and metabolites are excreted primarily in the urine and faeces. However, the main route of excretion is isomer dependent. The BAS are readily absorbed from the GI tract, rapidly metabolised to sulfophenyl carboxylates and excreted primarily in the bile (REACHh). The limited evidence available shows that dermal absorption of LAS and BAS is low, although prolonged contact may compromise the dermal barrier and allow increased absorption to occur (NICNASa; NICNASb; REACHi).

Acute Toxicity

Oral

Based on available data, the chemicals in this group are considered to have low acute toxicity following oral exposure.

Data from various animal studies reported the following median lethal doses (LD50):

- >2000 mg/kg bw for one calcium salt of BAS in this group (CAS No. 11117-11-6) (IUCLIDf; REACHh);
- >5000 mg/kg bw/day for two petroleum based chemicals in this group (CAS Nos. 61789-86-4 and 68783-96-0) (US EPA, 2005); and

- >16,000 mg/kg bw for one magnesium salt of LAS in this group (CAS No. 71786-47-5) (US EPA, 2005).

The low acute toxicity is supported by data on two LAS/BAS not on AICS, CAS Nos. 115733-09-0 and 71549-79-6 (US EPA, 2005).

Dermal

Overall, the dermal acute toxicity data for the calcium and magnesium alkyl benzenesulfonates generally indicate low acute dermal toxicity.

The LD50 for several LAS in this group (CAS Nos. 61789-86-4, 68783-96-0, 70024-69-0) was greater than 2000 mg/kg bw in rats and rabbits (US EPA, 2005). Observed sub-lethal effects included erythema and/or oedema, alopecia, matted fur and flaky skin at or around the test site. No signs of systemic toxicity were reported.

The low acute toxicity is supported by data on an LAS/BAS not on AICS, CAS No. 115733-09-0 (US EPA, 2005), a substance described as 'C14-C24 alkaryl calcium salt derivatives' (REACHa-g).

In an acute dermal toxicity study (OECD Test Guideline (TG) 402), the LD50 of a branched alkylsulfonate calcium salt in this group (CAS No. 11117-11-6) was between 1000 and 1600 mg/kg bw in rats (IUCLIDf; REACHh). Local signs included erythema (redness), fine and coarse scales, desquamations and scars. Systemic signs of toxicity included impaired respiration, motility and reflexes, stupor, prone position, trembling, hypothermia, narrowed palpebral fissures, and blood-encrusted snouts, all of which had resolved within eight days after application. However, this result is not consistent with the acute oral toxicity of this chemical, the low dermal absorption of alkylbenzenesulfonates and data available for other chemicals in this group, and may be associated with local effects.

Inhalation

Based on the available data the chemicals are considered to have low acute toxicity following inhalation exposure.

No mortality was observed in acute inhalation toxicity studies with the following chemicals:

- sulfonic acids, petroleum, calcium salts (CAS No. 61789-86-4);
- sulfonic acids, petroleum, calcium salts, overbased (CAS No. 68783-96-0);
- sulfonic acids, petroleum, magnesium salts (CAS No. 61789-87-5); and
- benzenesulfonic acid, mono-C16-24-alkyl derivatives, calcium salts (CAS No. 70024-69-0).

In these studies, rats were exposed (whole body) to an aerosol of the substance at a nominal atmospheric concentration of 1.9 mg/L for four hours. Observed sub-lethal effects included reduced activity, lacrimation, nasal discharge, matted coat, hunched appearance, soft stools, closed eyes and respiratory signs. The effects generally abated within two weeks. No signs of systemic toxicity were reported (US EPA, 2005; REACHf-g; REACHi).

Corrosion / Irritation

Skin Irritation

Based on the available data for some of the chemicals in this group and analogue chemicals, the chemicals in this group are considered to be skin irritants and warrant hazard classification (refer to **Recommendation** section).

Benzenesulfonic acid, C10-60-alkyl derivatives, calcium salts (CAS No. 90194-27-7) was applied to the abraded and intact skin of New Zealand White (NZW) rabbits for 24 hours (OECD TG 404). Slight to severe erythema and moderate to severe oedema were reported at the tested concentration (41 %). The effects subsided by day 9 after application (IUCLID, 2000a).

Undiluted benzenesulfonic acid, mono-C16-24-alkyl derivatives, calcium salts (CAS No. 70024-69-0) was tested in NZW rabbits (n = 3/ study) in a primary dermal irritation study. The chemical induced slight erythema and oedema 24, 48 and 72 hours after application. The effects were completely reversed by day 14 (REACHc; REACHg; REACHi).

Undiluted benzenesulfonic acid, mono-C19-28-alkyl derivatives, calcium salts, overbased (CAS No. 70024-72-5) was applied to rabbit skin for 4 hours (OECD TG 404). The animals were observed at 24 and 72 hours after application. The primary irritation index was obtained at 2.5 (equivalent to a moderate skin irritant). No other details were reported (IUCLID, 2000c).

In several studies, the chemical sulfonic acids, petroleum, calcium salts was applied to NZW rabbit skin for 4 hours under semiocclusive conditions (OECD TG 404). The animals were observed up to 78 hours after application. The test substance induced slight erythema and oedema (REACHf).

Numerous skin irritation studies available for analogue chemicals (LAS) support hazard classification for these chemicals as skin irritants (NICNASa).

Eye Irritation

Limited data are available for the chemicals. More extensive data are available for analogue chemicals. Based on weight of evidence, the chemicals are considered to potentially cause eye irritation but data do not support hazard classification.

Benzenesulfonic acid, C10-60-alkyl derivatives, calcium salts (CAS No. 90194-27-7) was applied to the eyes of NZW rabbits (OECD TG 405). After 24 hours, all animals showed slight to moderate redness, swelling or discharge at the tested concentration (41 %). No effects were reported in the cornea or the iris at any time. The effects were completely reversed in one animal by 48 hours and in all animals by day 4 after application. No scores were reported (IUCLID, 2000a).

Undiluted benzenesulfonic acid, mono-C16-24-alkyl derivatives, calcium salts (CAS No. 70024-69-0) and sulfonic acids, petroleum, magnesium salts (CAS No. 61789-87-5) were tested in the eyes of six NZW rabbits in two separate acute eye irritation studies. In both studies, a dose of 0.1 mL was instilled into the eyes and not washed out. Treated eyes were examined at days 1, 2 and 3 after treatment. Mean scores for each animal for corneal opacity and iritis was 0 in all cases. The scores for conjunctival redness and oedema were less than 2 in all of the animals. All eyes were cleared of irritation within seven days of treatment (REACHc; REACHg).

Three studies (OECD TG 405) in rabbits reported the undiluted chemical, benzenesulfonic acid, mono-C19-28-alkyl derivatives, calcium salts, overbased (CAS No. 70024-72-5) as an irritant based on Draize scores (5.56, 3.22, 5.44). No corneal or iridal effects were reported. No other details were reported (IUCLID, 2000c).

In an eye irritation study in rabbits (OECD TG 405) undiluted sulfonic acids, petroleum, calcium salts (CAS No. 61789-86-4) was determined to be slightly irritating. A dose of 0.1 mL was instilled into the eyes and not washed out. Treated eyes were examined at 24, 48 and 72 hours post-treatment. Mean scores at days 1, 2 and 3 for each animal for corneal opacity and iritis was 0 in all cases. The scores for conjunctival redness and chemosis were less than 2 in all animals.

Sensitisation

Skin Sensitisation

Based on weight of evidence, the chemicals in this group are not considered to be skin sensitisers. In several skin sensitisation studies for members of this group (CAS Nos. 61789-86-4, 70024-72-5 and 90194-27-7) tested using the guinea pig Buehler method, the chemicals were reported as sensitisers at high induction concentrations. This effect was not confirmed for the chemicals CAS Nos. 70024-72-5, 90194-27-7, 71786-47-5 and 11117-11-6 in local lymph node assay (LLNA), guinea pig maximisation test (GPMT), Buehler test or human exposure studies. Furthermore, there are no chemical structural alerts for sensitisation for the chemicals. Analogue chemicals (LAS) are not considered to be skin sensitisers (NICNASa; NICNASb).

Two studies in guinea pigs (Buehler test, OECD TG 406) examined the skin sensitisation potential of the chemicals (IUCLID, 2000a; IUCLID, 2000c). The animals (20/group) were induced at concentrations of either 1, 10 or 100 % followed by a challenge at concentrations of either 1 or 5 %. No positive reactions were observed at the induction concentration of either 1 or 10 %,

although the undiluted chemical was found to be sensitising. No other details were available. In another Buehler test (OECD TG 406), benzenesulfonic acid, mono- and dialkyl derivatives, magnesium salts (CAS No. 71786-47-5) was not found to be sensitising in guinea pigs induced at 100 % and challenged at 50 % (REACHg). In a GPMT (OECD TG 406), benzenesulfonic acid, tetrapropylene-, calcium salt (CAS No. 11117-11-6) did not induce skin sensitisation when induced (intradermally and dermally at 0.2% and 3% in petrolatum, respectively) and challenged at 0.1% in petrolatum (IUCLIDf; REACHh).

For the chemical sulfonic acids, petroleum, calcium salts (CAS No. 61789-86-4) there are several studies indicating positive sensitisation responses in the Buehler test in guinea pigs (OECD TG 406) with induction concentrations up to 100% followed by challenge concentrations up to 60 %. LLNA study in mice (OECD TG 429) at concentrations of 0.1, 1, 10 or 30 % in dimethylformamide (4 animals per dose) reported stimulation indices as 3.75, 3.0, 10.16, 20.44, which indicate a sensitisation response.

It has been reported that LAS may be weak sensitisers in guinea pigs under exaggerated exposure conditions (i.e. under high concentrations of the test chemical), although clear no-effect levels were well below the anticipated exposure levels for the chemicals (Little, 1991). Additionally, the Buehler test has been associated with false positives (e.g. for another anionic surfactant—sodium lauryl sulfate) (Basketter & Kimber, 2010).

Using an enhanced LLNA method, Signs and DeGeorge (2014) were able to show that long chain (C15–30) alkylbenzene calcium sulfonates may have the potential to produce a false positive reaction in an LLNA, which may be due to the dermal irritation properties of the chemicals.

Observation in humans

In two Human Repeat Insult Patch Tests (HRIPT), the chemical (CAS No. 70024-72-5) was applied at either 1 or 10 % concentrations to 104 volunteers. The 24-hour exposure was repeated nine times during the induction period. After a two-week rest period, a 24-hour challenge patch was applied. No evidence of skin sensitisation was reported (IUCLID, 2000c).

In three different extensive patch test studies, volunteers were induced with 10 (n=199), 30 (n=47) and 100 % (n=48) of the chemical (CAS No. 70024-72-5) for 24 hours nine times during the induction period. After a 2-week rest period, a 24-hour challenge patch was applied. Ambiguous evidence of sensitisation was observed in the 30 and 100 % chemical groups. Volunteers who tested positive with the 10 % (induction) concentration did not produce any positive response when further rechallenged with 1 % of the chemical (IUCLID, 2000c).

In one HRIPT, the chemical (CAS No. 61789-86-4) was applied at 1 % concentration to 53 volunteers. The 24-hour exposure was repeated nine times during the induction period. After a two-week rest period, a 24-hour challenge patch was applied and monitored at 24 and 72 hours post challenge application. No evidence of skin irritation or sensitisation was reported (REACHf).

Additionally, HRIPT data for analogue chemicals (LAS) show no clear evidence of skin sensitisation (NICNASa; NICNASb, REACHg).

Repeated Dose Toxicity

Oral

Based on weight of evidence from available data for analogue chemicals, the chemicals in this group are not likely to cause serious damage to health from repeated oral exposure.

In a 90 day study comparing oral toxicities of BAS and LAS, a no observed adverse effect level (NOAEL) of 50 mg/kg bw/day was determined for both groups in rats (REACHh). At the highest test dose of 250 mg/kg bw/day, increased caecal weights were seen in males of LAS test group; and increased liver weights were seen in both LAS and BAS test groups.

In two separate 28-day repeat dose oral toxicity studies in rats (OECD TG 407), a NOAEL of 500 mg/kg bw/day was reported for both benzenesulfonic acid, mono-C16-24-alkyl derivatives, calcium salts (CAS No. 70024-69-0) and C20–24 alkaryl calcium salt derivative (CAS No. not specified) (NICNAS, 2004; US EPA, 2005; REACHg). A reduction in mean cholesterol values was seen in rats (both sexes) at the next test dose of 1000 mg/kg bw/day for both chemicals.

In a study with analogue chemical benzenesulfonic acid, C14–24-branched and linear alkyl derivatives, calcium salts (CAS No. 115733-09-0), a NOAEL of 150 mg/kg bw/day was assigned based on the presence of stomach ulceration and inflammation in female rats at the next test dose of 500 mg/kg bw/day (US EPA, 2005).

Similar local irritancy effects were observed in studies of up to two years duration, for analogue chemicals (LAS and LASA), with reported NOAEL values ranging from 40–1000 mg/kg bw/day (NICNASa; NICNASb; REACHI).

Dermal

Based on weight of evidence from the available studies for the chemicals in this group and analogue chemicals, the chemicals are not likely to cause serious damage to health from repeated dermal exposure (NICNASa; NICNASb).

The chemicals in this group (CAS Nos. 71786-47-5, 61789-87-5 and 68783-96-0) were evaluated in separate 28-day repeated dose dermal toxicity studies in rabbits (OECD TG 410). No treatment-related deaths or systemic effects were recorded. Local cutaneous responses, characterised by desquamation and hyperkeratosis, were seen in some animals. A NOAEL of 1000 mg/kg bw/day for systemic toxicity was established for both chemicals (NICNAS, 2004; US EPA, 2005; REACHg).

In a non-guideline study in rabbits with one of the chemicals in this group (CAS No. 71786-47-5), local and systemic effects were observed following topical exposure to 2 mL/kg/day of the test substance in a Primol 205 vehicle at concentrations of 0, 25 and 100 % (w/v) for six hours/day, five days/week for 28 days. Effects included skin irritation, reduced body weights, changes in haematological parameters and effects in the testes and epididymis. A NOAEL was not established (NICNAS, 2004; US EPA, 2005).

In a well performed 28-day dermal toxicity study in male Sprague Dawley (SD) rats, the chemical (CAS No. 61789-86-4) was applied undiluted at 1000 mg/kg bw/day (66 animals) for six hours, five days/week under occlusive conditions. No treatment related systemic effects were reported (REACHf).

Analogue chemicals (LAS) produced no treatment-related systemic effects in repeat dose dermal toxicity studies in rats (NICNASa; NICNASb).

Inhalation

Based on available data, the chemicals are not likely to cause serious damage to health from repeated inhalation exposure.

Inhalation toxicity (28-day) was evaluated in rats (OECD TG 412) for the following chemicals:

- sulfonic acids, petroleum, calcium salts, overbased (CAS No. 68783-96-0);
- sulfonic acid, petroleum, calcium salts (CAS No. 61789-86-4);
- sulfonic acids, petroleum, magnesium salts (CAS No. 61789-87-5); and
- benzenesulfonic acid, propenated, calcium salt, overbased (CAS No. 68610-84-4).

Animals were exposed (whole-body) to concentrations of 49.5, 156 or 260 mg/m³ (CAS Nos. 68783-96-0 and 68610-84-4) or 50, 150, or 250 mg/m³ (CAS Nos. 61789-86-4 and 61789-87-5) for six hours/day, five days/week, for four weeks. In all of the studies, red nasal discharge, matted coat and decreased activity were noted at the two highest concentrations. Dose-related increases in the lung weight with corresponding microscopic changes (evidence of intralobular macrophage accumulation and bronchiole epithelial hyperplasia/hypertrophy) were reported at the two highest concentrations. Based on these effects, a No Observed Adverse Effect Concentration (NOAEC) of 49.5 mg/m³ was established for CAS Nos. 68783-96-0 and 68610-84-4, and a NOAEC of 50 mg/m³ was established for CAS Nos. 61789-86-4 and 61789-87-5. (US EPA, 2005; REACHb; REACHf–g; REACHI).

Genotoxicity

Based on weight of evidence from available in vitro and in vivo studies for the chemicals in this group and analogue chemicals, the chemicals are not likely to be genotoxic.

The following in vitro data are available:

Some of the chemicals in this group (CAS numbers 61789-86-4, 68783-96-0, 70024-69-0 and 71786-47-5) and analogue chemicals, C20–24 alkaryl calcium salt derivative (CAS number not specified) and benzenesulfonic acid, dodecyl-, branched, calcium salts (CAS No. 70528-83-5) (not on AICS) gave negative results in a bacterial reverse mutation tests (Ames test/ OECD TG 471) in *Salmonella typhimurium*. The chemical C20–24 alkaryl calcium salt derivative (CAS no. not specified) also gave negative results in *Escherichia coli* (strain WP2uvrA) with and without metabolic activation (US EPA, 2005; IUCLIDf; REACHc; REACHf–g).

Sulfonic acids, petroleum, calcium salts, overbased (CAS No. 68783-96-0) was tested for its potential to induce point mutations in cultured mouse lymphoma L5178Y cells, both in the presence and absence of S9 mix prepared from Aroclor-induced rat liver. No changes in mutation frequency were seen up to the highest dose tested—5000 µg/mL (REACHb). The chemical was also negative in an in vitro chromosome aberration study in Chinese hamster lung (CHL) cells, both in the absence and presence of metabolic activation (REACHb). Benzenesulfonic acid, methyl-, mono-C20-24-branched alkyl derivs., calcium salts (CAS No. 722503-68-6) gave negative results for chromosomal aberrations in human whole blood lymphocytes with and without metabolic activation in a guideline study (OECD TG 471) (REACHi).

The following in vivo data are available:

Sulfonic acids, petroleum, calcium salts (CAS No. 61789-86-4), benzenesulfonic acid, mono-C16-24-alkyl derivatives, calcium salts (CAS No. 70024-9-0), C20–24 alkaryl calcium salt derivative (CAS No. not specified), benzenesulfonic acid, 4-C10-13-sec-alkyl derivatives (CAS No. 85536-14-7), and benzenesulfonic acid, methyl-, mono-C20-24-branched alkyl derivs., calcium salts (CAS No. 722503-68-6) gave negative results in separate in vivo mouse micronucleus assays (US EPA, 2005; REACHc; REACHf–i).

Analogue chemicals (LAS and LASA) are also not considered to be genotoxic (NICNASa; NICNASb).

Carcinogenicity

No data are available for the chemicals in this group. Based on weight of evidence from available carcinogenicity studies for analogue chemicals (LAS), in which there was no evidence of tumorigenesis (NICNASa), and considering the low toxicity of the calcium and magnesium cations, the chemicals in this group are not likely to be carcinogens.

Reproductive and Developmental Toxicity

No data are available for the chemicals in this group. Based on weight of evidence from available studies for analogue chemicals, the chemicals in this group are not likely to cause specific reproductive or developmental toxicity.

In an oral one-generation reproduction toxicity study (OECD TG 415) with C14–C24 alkaryl calcium salt (CAS No. 115733-09-0, not listed on AICS) at up to 500 mg/kg, no effects on fertility, litter size, lactation or survival of offspring in SD rats were observed (US EPA, 2005; REACHg; REACHi). A similar study (OECD TG 415) determining the effects of benzenesulfonic acid, C14 -C24 branched & linear alkyl derivatives, calcium salts in rats reported a NOAEL of 500 mg/kg bw/day (highest dose tested) for parental and developmental toxicity (REACHi).

Benzenesulfonic acid, C10–16-alkyl derivatives, magnesium salts (CAS No. 68584-26-9, not listed on AICS) administered to rats continuously in their diet at 103 and 222 mg/kg bw/day for two generations had no adverse effects on reproduction or fertility. The NOAEL for reproductive effects was >222 mg/kg bw/day. The developmental NOAEL based on the growth of F2 pups from birth to weaning was 50 mg/kg bw/day (US EPA, 2008).

In a three generation reproductive study, sodium salt LAS (C10-14) (CAS No. unknown) was fed for 84 days to 4 groups of weanling rats (strain not specified) for two years (three generations). The NOAEL for parental and the two offspring generations was determined to be 350 mg/kg bw/day (0.5 %), which was the highest dose tested (REACHh).

In a developmental toxicity study, maternal and developmental NOAELs of 300 mg/kg bw/day were reported for a sodium salt of LAS (C11-12) (CAS No. unknown) in CD rats dosed orally between gestation days (GD) 6 to 15 (REACHh). Maternal toxicity included retarded weight gain and transient diarrhoea in the highest dose group (600 mg/kg bw). There were no significant effects on foetal development except for marginal retardation of ossification of the sternum at the highest dose tested.

Three toxicity studies in which pregnant rabbits or rats were exposed to analogue chemical (CAS No. 68584-26-9) during GD 6–18 reported no developmental effects in the offspring (US EPA, 2008).

Analogue chemicals, LAS and LASA, are not considered to cause specific reproductive or developmental toxicity. Any developmental effects were only observed secondary to maternal toxicity (NICNASa; NICNASb).

Risk Characterisation

Critical Health Effects

The critical health effect for risk characterisation for this group of chemicals is skin irritation. The chemicals may also cause transient eye irritation.

Public Risk Characterisation

The available use information indicates that these chemicals may be present in cosmetics and domestic products (including cleaning products, detergents and auto products). Other surfactants may also be present in products containing these chemicals. The main routes of public exposure to these chemicals are expected to be through the skin or by accidental ingestion via the mouth.

Although no concentration information was available regarding the use of these chemicals in cosmetics, based on related LAS chemicals, only low concentrations in cosmetics are expected (NICNASa). Therefore, skin and eye irritant effects are not expected and the risk to public health from this use is not considered to be unreasonable and further risk management is not considered necessary for public safety.

Available data (refer to **Import, manufacture and use: International** section) indicate that the chemicals are only used in domestic products at low concentrations. Therefore skin and eye irritant effects are not expected. Provided that normal precautions are taken to avoid prolonged eye and skin contact, public health risk posed by domestic products containing the chemicals is not considered to be unreasonable.

Occupational Risk Characterisation

During product formulation, dermal exposure might occur, particularly where manual or open processes are used. These may include transfer and blending activities, quality control analysis, and cleaning and maintaining equipment. Worker exposure to the chemicals at lower concentrations could also occur while using formulated products containing the chemicals. The level and route of exposure will vary depending on the method of application and work practices employed.

The chemicals in the group could pose an unreasonable risk to workers, unless adequate control measures to minimise dermal exposure to the chemicals are implemented, particularly at high concentrations. The chemicals should be appropriately classified and labelled to ensure that a person conducting a business or undertaking (PCBU) at a workplace (such as an employer) has adequate information to determine appropriate controls.

The data available support an amendment to the hazard classification (see **Recommendation** section) for these chemicals.

NICNAS Recommendation

Assessment of the chemicals is considered to be sufficient, provided that the recommended amendment to the classification and labelling is adopted, and all other requirements are met under workplace health and safety and poisons legislation as adopted

by the relevant state or territory.

Regulatory Control

Work Health and Safety

The chemicals in this group are recommended for classification and labelling aligned with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) as below.

This assessment does not consider classification of physical hazards and environmental hazards. These are outside the scope of this assessment and any existing HCIS classifications in those categories are not recommended to be changed.

The recommended classification is based on read across principles (see **Grouping rationale** section) and should be used as a default for all members of the group. If empirical data become available for any member of the group indicating that a lower (or higher) classification is appropriate for a specific chemical, these may be used to amend the default classification for that chemical.

From 1 January 2017, under the model Work Health and Safety Regulations, chemicals are no longer to be classified under the Approved Criteria for Classifying Hazardous Substances system.

Hazard	Approved Criteria (HSIS) ^a	GHS Classification (HCIS) ^b
Irritation / Corrosivity	Not Applicable	Causes skin irritation - Cat. 2 (H315)

^a Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].

^b Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third Edition.

* Existing Hazard Classification. No change recommended to this classification

Advice for consumers

Products containing these chemicals should be used according to the instructions on the labels.

Advice for industry

Control measures

Control measures to minimise the risk from dermal exposure to the chemical should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate, or minimise risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemical is used. Examples of control measures that could minimise the risk include, but are not limited to:

- using closed systems or isolating operations;
- health monitoring for any worker who is at risk of exposure to the chemical, if valid techniques are available to monitor the effect on the worker's health;
- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;

- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemical.

Guidance on managing risks from hazardous chemicals are provided in the *Managing risks of hazardous chemicals in the workplace—Code of practice* available on the Safe Work Australia website.

Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Obligations under workplace health and safety legislation

Information in this report should be taken into account to help meet obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((M)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of the chemical are prepared; and
- managing risks arising from storing, handling and using a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (M)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation of safety data sheets for hazardous chemicals—Code of practice* and *Labelling of workplace hazardous chemicals—Code of practice*, respectively. These codes of practice are available from the Safe Work Australia website.

A review of the physical hazards of the chemical has not been undertaken as part of this assessment.

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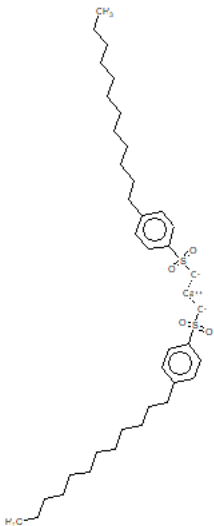
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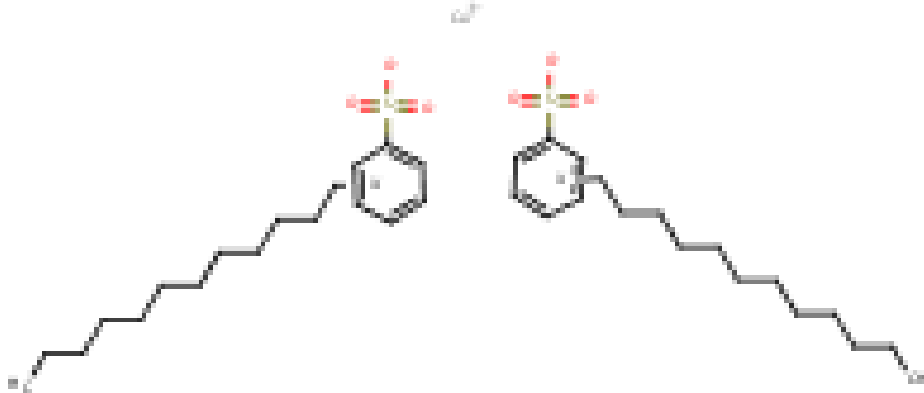
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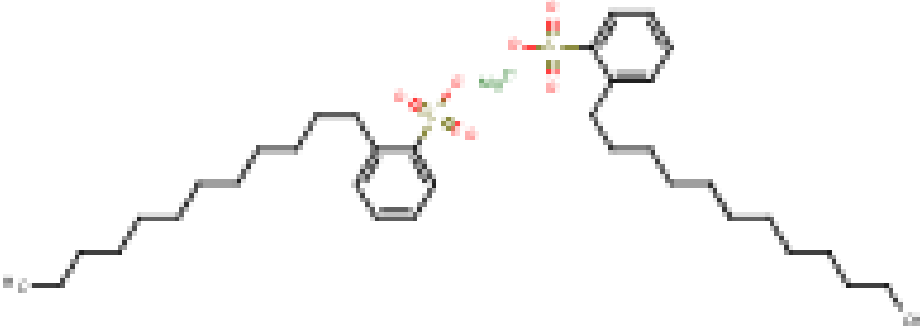
Chemical Identities

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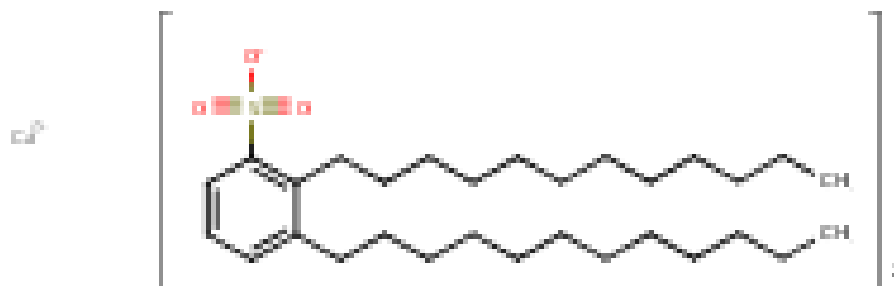
Molecular Weight	693
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CAS Number	26264-06-2
Structural Formula	
Molecular Formula	C ₁₈ H ₃₀ O ₃ S.1/2Ca
Molecular Weight	693

Chemical Name in the Inventory and Synonyms	Benzenesulfonic acid, dodecyl-, magnesium salt magnesium dodecylbenzenesulphonate benzenesulfonic acid, dodecyl-, magnesium salt (2:1)
CAS Number	27479-45-4

Structural Formula	
Molecular Formula	C18H30O3S.1/2Mg
Molecular Weight	675.3

Chemical Name in the Inventory and Synonyms	Benzenesulfonic acid, didodecyl-, calcium salt calcium bis(didodecylbenzenesulphonate)
CAS Number	29299-35-2
Structural Formula	



Molecular Formula	C30H54O3S.1/2Ca
Molecular Weight	1027.70

Chemical Name in the Inventory and Synonyms	Sulfonic acids, petroleum, calcium salts calcium petroleum sulfonate petroleum sulfonic acids, calcium salts
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Structural Formula	No Structural Diagram Available

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Molecular Weight	Unspecified

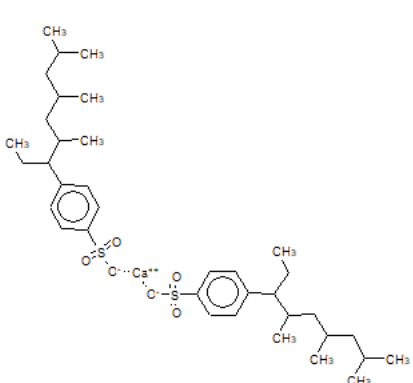
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Structural Formula	

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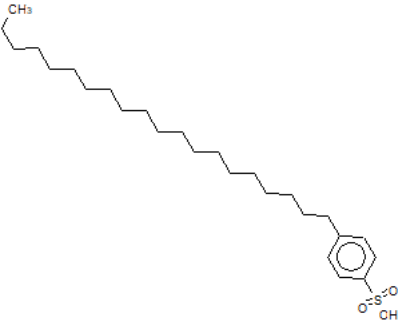
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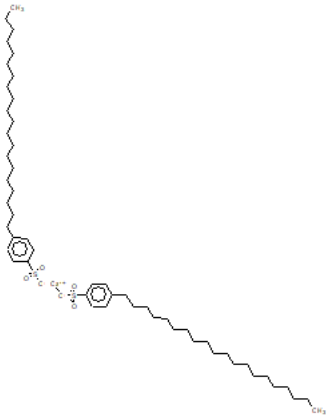
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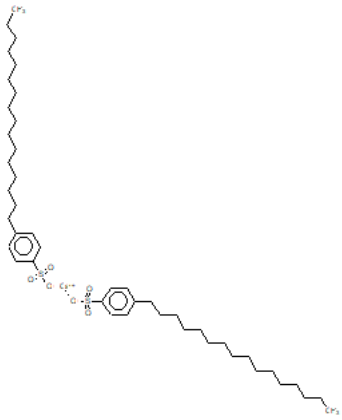
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Molecular Weight	Unspecified

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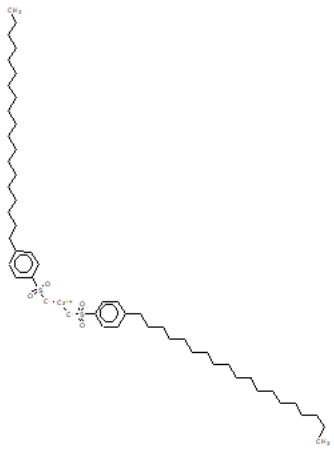
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Structural Formula	

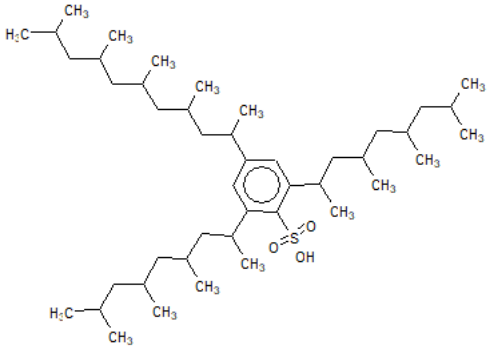
	
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Molecular Weight	Unspecified

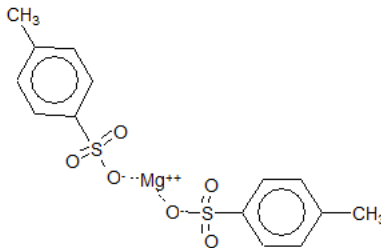
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Structural Formula	
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Molecular Weight	Unspecified

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Structural Formula	
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Molecular Weight	Unspecified

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Structural Formula	

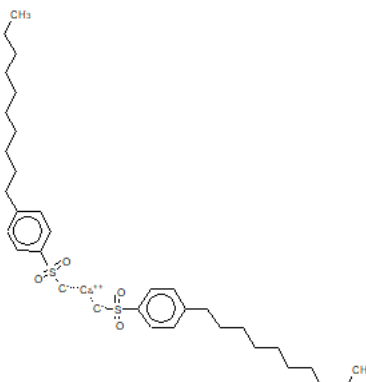
	
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Molecular Weight	Unspecified

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Molecular Weight	Unspecified

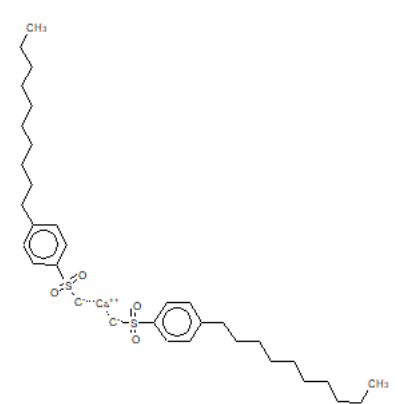
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Molecular Weight	Unspecified

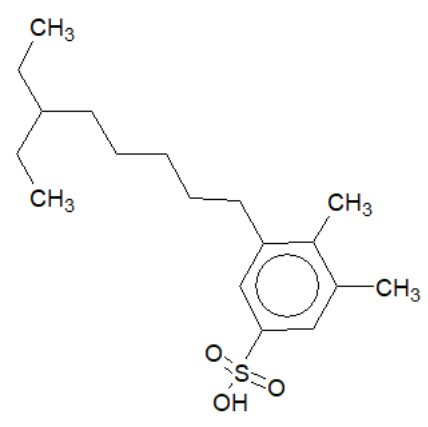
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Structural Formula	<p style="text-align: center;">No Structural Diagram Available</p>

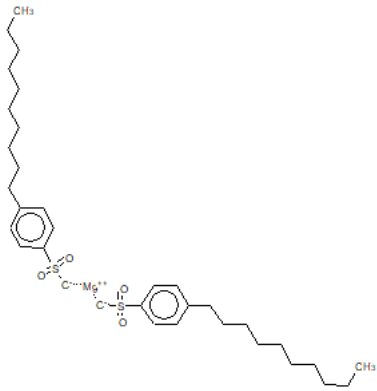
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Molecular Weight	Unspecified

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Molecular Weight	Unspecified

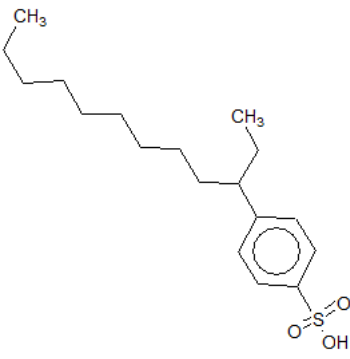
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Structural Formula	

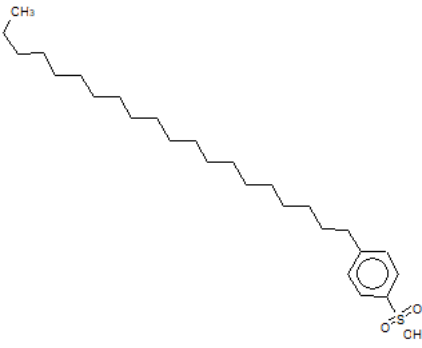
	
Molecular Formula	Unspecified
Molecular Weight	Unspecified

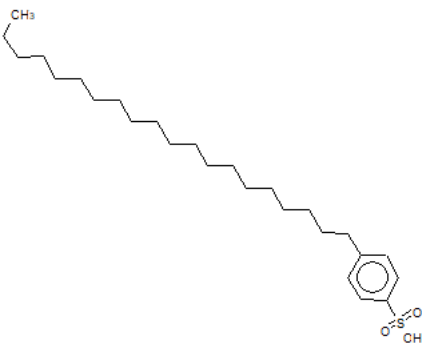
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Structural Formula	
Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	Benzenesulfonic acid, C10-60-alkyl derivatives, magnesium salts magnesium mono- and di-C10-60-alkylbenzene sulfonate
CAS Number	93028-29-6
Structural Formula	
Molecular Formula	Unspecified
Molecular Weight	Unspecified

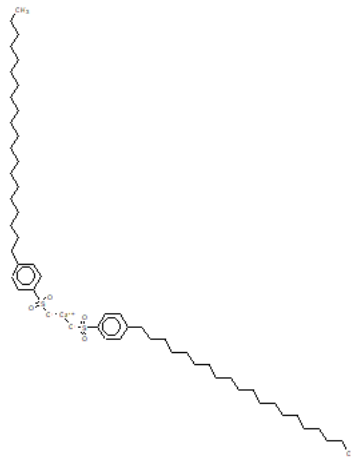
Chemical Name in the Inventory and Synonyms	Benzenesulfonic acid, mono-C10-13-sec-alkyl derivatives, calcium salts
CAS Number	97467-80-6
Structural Formula	

	
Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	Benzenesulfonic acid, C20-30-alkyl derivatives, calcium salts calcium alkyl-C20-30-benzenesulfonate
CAS Number	103213-14-5
Structural Formula	
Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	Benzenesulfonic acid, C20-30-alkyl derivatives, magnesium salts magnesium C20-30-alkylbenzenesulfonate
CAS Number	103213-15-6
Structural Formula	
Molecular Formula	Unspecified
Molecular Weight	Unspecified

Chemical Name in the Inventory and Synonyms	Benzenesulfonic acid, mono-C20-24-alkyl derivs., calcium salts C20-24-alkyl benzenesulfonic acid,calcium salt
CAS Number	156105-31-6
Structural Formula	



Molecular Formula	Unspecified
Molecular Weight	Unspecified

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