Australian Government
Department of Health and Aged Care
Australian Industrial Chemicals Introduction Scheme

Benzenesulfonic acid, dodecyl-, compound with 4,4-dimethyloxazolidine (1:1)

Evaluation statement

26 June 2024

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Subject of the evaluation

Benzenesulfonic acid, dodecyl-, compound with 4,4-dimethyloxazolidine (1:1)

Chemical in this evaluation

Name	CAS registry number
Benzenesulfonic acid, dodecyl-, compound with 4,4-dimethyloxazolidine (1:1)	68084-53-7

Reason for the evaluation

Evaluation Selection Analysis indicated a potential human health risk.

Parameters of evaluation

The chemical is listed on the Australian Inventory of industrial Chemicals (the Inventory). The evaluation is a human health risk assessment for all identified industrial uses of the chemical.

Summary of evaluation

Summary of introduction, use and end use

There is currently no specific information about the introduction, use and end use of the chemical in Australia.

Limited data available internationally indicate it is used as a process regulator in chemical and paints and coatings manufacture. Based on function and use data for the chemical's salt components, the chemical has potential applications in a variety of uses. Linear alkyl benzene sulfonates (LAS) are surfactants and the counter ion dimethyl oxazolidine (CAS No. 51200-87-4) is a formaldehyde releasing preservative. There is no evidence that the chemical is used in products available to the public.

Human health

Summary of health hazards

No hazard data are available for the chemical. Data for other linear alkylbenzenesulfonates (LAS), dodecylbenzenesulfonic acid and the counterion dimethyl oxazolidine have been used to infer the toxicity of the chemical. In addition, the hydrolysis product, formaldehyde is considered a critical driver of toxicity due to its formation under physiological conditions or when the chemical is in solution. The surfactant nature of the chemical will also likely contribute to local effects.

The previous assessments for LAS, dodecylbenzenesulfonic acid and dimethyl oxazolidine should be read in conjunction with this evaluation statement (AICIS 2023; NICNAS 2014; NICNAS 2018).

Based on the available data, the chemical is not:

- expected to cause serious systemic health effects following repeated exposure
- expected to be carcinogenic
- considered to have genotoxic potential
- considered to have reprotoxic or developmental toxicity.

Based on data for LAS and dimethyl oxazolidine the chemical is expected to have moderate acute oral and inhalation toxicity, warranting classification. Oral median lethal dose (LD50) values were reported in the range 400–1500 mg/kg bw/day. Mortalities occurred at 11.6 mg/L in a 1-hour inhalation study with dimethyl oxazolidine and in an acute inhalation toxicity study with LAS at 0.31 mg/L. There is insufficient information to determine whether the chemical is acutely toxic via the dermal route.

In the pure form the chemical is expected to have similar skin and eye irritation potential to other LAS. Based on data for LAS with a variety of counterions the chemical is expected to be at least irritating to skin and cause severe eye damage.

In solution, the irritation potential of the chemical will depend on the levels of dodecylbenzenesulfonic acid and formaldehyde. Linear alkylbenzene sulfonic acids are corrosive to skin and formaldehyde solutions are regarded as corrosive. Sensory irritation from formaldehyde vapour release is not expected from end use products containing the chemical. During formulation of the products, formaldehyde gas could be present.

Based on data for formaldehyde, which is a strong skin sensitiser in solutions, the chemical is expected to be a skin sensitiser, warranting hazard classification

For further details of the health hazard information see **Supporting Information.**

Hazard classifications relevant for worker health and safety

The chemical satisfies the criteria for classification according to the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (UNECE 2017) for hazard classes relevant for work health and safety as follows. This does not consider classification of physical hazards and environmental hazards.

In solution the classification should be based on levels of dodecylbenzenesulfonic acid and formaldehyde.

Health hazards	Hazard category	Hazard statement
Acute toxicity (oral)	Acute Tox. 4	H302: (Harmful if swallowed)
Acute toxicity (inhalation)	Acute Tox. 4	H332: (Harmful if inhaled)
Skin corrosion/irritation	Skin Irrit. 2	H315: Causes skin irritation
Serious eye damage/eye irritation	Eye Damage 1	H318: Causes serious eye damage
Skin Sensitisation	Skin Sens. 1	H317: (May cause an allergic skin reaction)

Summary of health risk

Public

Based on the functions of the components of the chemical as surfactant and preservative, the chemical may have a similar function in consumer products. However, since there is limited use information available, the use of the chemical is not expected to be widespread. Therefore, there are no identified risks to the public that require management.

If the chemical is used in products available to the public, current regulatory controls limit the amount of free formaldehyde in consumer products, including that released from formaldehyde donors.

Workers

During product formulation and manufacture, dermal, ocular and inhalation exposure of workers to the chemical may occur, particularly where manual or open processes are used. These may include transfer and blending activities, quality control analysis, cleaning and maintenance of equipment. Worker exposure to the chemical at lower concentrations could also occur while using formulated products containing the chemical. The level and route of exposure may vary depending on the method of application and work practices employed. Good hygiene practices to minimise incidental oral exposure are expected to be in place.

Given the critical local effects and systemic health effects following acute exposure, the chemical could pose a risk to workers. Control measures to minimise dermal, ocular and inhalation effects are needed to manage the risk to workers (see **Proposed means for managing risk** section).

Proposed means for managing risk

Workers

Recommendation to Safe Work Australia

It is recommended that Safe Work Australia (SWA) update the Hazardous Chemical Information System (HCIS) to include classifications relevant to work health and safety.

Information relating to safe introduction and use

The information in this statement should be used by a person conducting a business or undertaking at a workplace (such as an employer) to determine the appropriate controls under the relevant jurisdiction Work Health and Safety laws.

Control measures that could be implemented to manage the risks arising from ocular, dermal and inhalation exposure to the chemical include, but are not limited to:

- using closed systems or isolating operations
- minimising manual processes and work tasks through automating processes
- adopting work procedures that minimise splashes and spills
- cleaning equipment and work areas regularly
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemical.

Measures required to eliminate or manage risk arising from storing, handling and using this hazardous chemical depends on the physical form and how the chemical is used.

These control measures may need to be supplemented with:

- conducting health monitoring for any worker who is at significant risk of exposure to the chemical if valid techniques are available to monitor the effect on the worker's health.

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.

Model codes of practice, available from the Safe Work Australia website, provide information on how to manage the risks of hazardous chemicals in the workplace, prepare an SDS and label containers of hazardous chemicals. Your Work Health and Safety regulator should be contacted for information on Work Health and Safety laws and relevant Codes of Practice in your jurisdiction.

Conclusions

The Executive Director proposes to be satisfied that the identified risks to human health from the introduction and use of the industrial chemical can be managed.

Note:

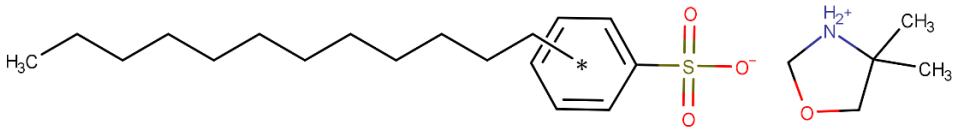
1. Obligations to report additional information about hazards under *Section 100* of the *Industrial Chemicals Act 2019* apply.
2. You should be aware of your obligations under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Supporting information

Chemical identity

Chemical name	Benzenesulfonic acid, dodecyl-, compound with 4,4-dimethyloxazolidine (1:1)
CAS No.	68084-53-7
Synonyms	4,4-dimethyloxazolidine dodecylbenzenesulfonate
Molecular formula	C23H41NO4S
Molecular weight (g/mol)	427.65
SMILES (canonical)	-
Chemical description	UVCB

Structural formula:



Relevant physical and chemical properties

No data are available. Based on data for other linear alkylbenzene sulfonates the chemical is expected to have low volatility.

Introduction and use

Australia

No specific information is available for the introduction, use and end use of this chemical in Australia.

International

Limited specific information is available for the introduction, use and end use of this chemical internationally. The chemical has reported use as a process regulator in the industry sectors of chemical manufacturing and paint and coating manufacturing (US EPA CDR 2020).

The likely function and use of the chemical can be inferred by the function and uses of the chemical's salt components.

Dimethyl oxazolidine (CAS No. 51200-87-4) is a formaldehyde releaser has reported use as a preservative in cosmetic, domestic and co mmercial uses (NICNAS 2018).

Linear alkylbenzene sulfonates (LAS) are anionic surfactants used in a range of consumer and industrial applications worldwide, predominantly in cleaning products. They also have use un cosmetics and commercial uses in coatings and paints, fillers, plasters, textile and leather finishing products (AICIS 2022).

Existing Australian regulatory controls

AICIS

No specific controls are currently identified for the chemical.

Public

This chemical is not specifically listed in the *Poisons Standard* (SUSMP) (TGA 2024). However, if the chemical is introduced or used in aqueous solution it falls under the scope of the following listings that apply to formaldehyde donors:

Formaldehyde donors are specifically included in the definition of free formaldehyde in the *Poisons Standard* (TGA 2024) as follows:

"Free formaldehyde" includes all hydrated and non-hydrated formaldehyde present in aqueous solution, including methylene glycol and formaldehyde released from formaldehyde donors.

Formaldehyde is listed in the *Poisons Standard* as follows (TGA 2024):

Schedule 2:

'FORMALDEHYDE (excluding its derivatives) for human therapeutic use **except**:

(a) in oral hygiene preparations containing 0.1% or less of free formaldehyde; or
(b) in other preparations containing 0.2% or less of free formaldehyde.'

Schedule 6:

'FORMALDEHYDE (excluding its derivatives) in preparations containing 0.05% or more of free formaldehyde **except**:

(a) for human therapeutic use;
(b) in oral hygiene preparations;
(c) in nail hardener cosmetic preparations containing 5% or more of free formaldehyde;
(d) in nail hardener cosmetic preparations containing 0.2% or less of free formaldehyde when labelled with the statement: PROTECT CUTICLES WITH GREASE OR OIL;
(e) in all other cosmetic preparations; or
(f) in other preparations containing 0.2% or less of free formaldehyde when labelled with the warning statement: CONTAINS FORMALDEHYDE.

Schedule 10:

'FORMALDEHYDE (excluding its derivatives):

(a) in oral hygiene preparations containing more than 0.1% of free formaldehyde;
(b) in aerosol sprays for cosmetic use containing 0.005% or more of free formaldehyde;
(c) in nail hardener cosmetic preparations containing 5% or more of free formaldehyde; or
(d) in all other cosmetic preparations containing 0.05% or more of free formaldehyde **except** in preparations containing 0.2% or less of free formaldehyde when labelled with the warning statement: CONTAINS FORMALDEHYDE.'

Schedule 2 chemicals are labelled with 'Pharmacy medicine' and are described as: 'substances, the safe use of which may require advice from a pharmacist and should be available from a pharmacy or, from a licensed person'.

Schedule 6 chemicals are labelled with 'Poison' and are described as: 'substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label'.

Schedule 10 chemicals are labelled with 'Substances of such danger to health as to warrant prohibition of sale, supply and use' and are described as: 'Substances which are prohibited for the purpose or purposes listed for each poison'.

Workers

The chemical is not listed on the HCIS (SWA n.d.).

No exposure standards are available for the chemical in Australia (SWA n.d.).

International regulatory status

No specific controls have been identified for this chemical.

Health hazard information

No toxicity data are available for this chemical. The chemical is a salt of two chemicals, dodecylbenzenesulfonic acid (CAS No. 27176-87-0, a linear long chain (C≥10) alkylbenzenesulfonate with surfactant properties and dimethyl oxazolidine (CAS No. 51200-87-4).

Data for other linear alkylbenzenesulfonates (LAS), dodecylbenzenesulfonic acid and dimethyl oxazolidine have been used to infer the toxicity of the chemical. The hydrolysis product, formaldehyde (CAS No. 50-00-0) is considered a critical driver for toxicity due to its formation under physiological conditions or if introduced in aqueous solutions. The surfactant nature of the chemical will likely contribute to local effects.

Several LAS with various counterions, dodecylbenzenesulfonic acid and dimethyl oxazolidine have been previously assessed under AICIS, and our former scheme, the National Industrial Chemicals Notification and Assessment Scheme (AICIS 2022; NICNAS 2014c; NICNAS 2018). These reports should be read in conjunction with this evaluation if further detail is needed.

Toxicokinetics

No data are available for the chemical. Based on data for its components, the chemical is expected to readily absorbed via the oral route. The dimethyl oxazolidine component of the chemical is expected to release formaldehyde in contact with water.

Dimethyl oxazolidine was reported to hydrolyse rapidly. Minor amounts of the parent chemical dimethyl oxazolidine were present soon after solution preparation. The hydrolysis products were formaldehyde and 2-amino-2-methyl-1-propanol (AMP), whereas AMP was reported to remain stable throughout the length of the 30-day study (US EPA 1996). Dimethyl oxazolidine has reported use as a preservative in cosmetics. The degree of completeness of formaldehyde release in a cosmetic product is dependent on the:

- concentration of the preservative in the product
- percentage of water in the product
- rate of formaldehyde release from the specific preservative
- length of time since formulation.

Linear alkylbenzene sulfonates (LASs) are readily absorbed through the gastrointestinal tract, are distributed throughout the body and are extensively metabolised. The parent compound and metabolites are excreted primarily in the urine and faeces. The limited evidence available shows that dermal absorption of LAS salts is low, with 0.1–0.6% of administered dose absorbed through intact skin. However, prolonged contact may compromise the dermal barrier and allow increased absorption to occur (IPCS 1996; AISE and Cefic 2013).

Oral administration of sodium salts of LAS (C12) to Wistar rats showed rapid distribution to:

- stomach
- intestines
- urinary bladder
- liver
- kidney
- testes
- spleen
- lung.

After 168 hours, 47–50% of the salts were excreted in urine and 50–51% in the faeces. Oral administration of LAS (C12) with various 2- and 4-substitution ratios showed marked differences in excretion. The 2-isomer was mainly excreted in urine (75%), while the 4-isomer was mainly excreted in the faeces (77.9%) (NICNAS 2014a).

Acute toxicity

Oral

No data are available for the chemical.

Based on data for LAS and dimethyl oxazolidine, the chemical is considered to be acutely toxic via the oral route – warranting classification.

Both salt components are classified as hazardous in the Hazardous Chemical Information System (HCIS) (SWA n.d.) as ‘Acute toxicity (oral) – Category 4’. The available data supports these classifications.

Dimethyl oxazolidine has a median lethal dose (LD50) of 956 mg/kg in rats (REACH n.d.-a, NICNAS 2018).

There are numerous study data available for LAS with a carbon range of C9-15 (IPCS 1996; AISE and Cefic 2013). LD50s of 404–1470 mg/kg bw in rats and 1250–2300 mg/kg bw in mice have been reported (REACH n.d.-b; NICNAS 2014a; NICNAS 2014b). Reported signs of toxicity include piloerection, diarrhoea, weakness and changes in motor activity. Convulsions, torsion and paralysis of the hind limbs were also observed in mice.

Dermal

No data are available for the chemical.

Dimethyl oxazolidine is classified as hazardous in the HCIS (SWA n.d.) as ‘Acute toxicity (dermal) - Category 4’. The available data support this classification with reported LD50 values between 970–2000 mg/kg bw (REACH n.d.-a; NICNAS 2018).

Sodium dodecylbenzenesulfonate (CAS No. 25155-30-0) has an LD50 of >2000 mg/kg bw (REACH n.d.-c). After administration, slight erythema and oedema were observed after 48 hours, with mortality reported. The reported LD50 in rabbits is >4199 mg/kg bw for benzenesulfonic acid, dodecyl-, compound with 2,2',2''-nitrilotris[ethanol] (1:1) (CAS No. 27323-41-7) (AICIS 2022).

Based on molecular weight, a 1:1 combination of the two ions would give 76% dodecylbenzenesulfonic acid and 24% dimethyloxazolidinone. Given that the lowest reported LD50 for dimethyloxazolidinone is 970 mg/kg bw, it is unlikely that a compound containing approximately a quarter of dimethyloxazolidinone would be acutely toxic via the dermal route. Although, effects cannot be ruled out.

Inhalation

No data are available for the chemical.

Limited data are available for other LAS and the counterion. Mortalities occurred at 11.6 mg/L in a 1-hour study with dimethyl oxazolidine and in acute inhalation toxicity study with a LAS at 0.31 mg/L. Based on this data, the chemical is considered acutely toxic via the inhalation route, warranting hazard classification.

Dimethyl oxazolidine is classified as hazardous in the HCIS (SWA n.d.) as ‘Acute toxicity (inhalation) – Category 4’. The available reported LC50 of 11.6 mg/L (1h) in rats support this classification (REACH n.d.-a; NICNAS 2018).

Acute inhalation toxicity data indicate that sodium dodecylsulfonate is moderately toxic, with mortality occurring at respirable particle concentrations at 0.31 mg/L (MMAD = 2.5 microns) (HERA 2013; NICNAS 2014).

Corrosion/Irritation

Skin irritation

No data are available for the chemical. Based on data for LAS and dimethyl oxazolidine the chemical (in pure form) it is at least irritating skin, warranting hazard classification. More severe effects such as corrosion cannot be fully ruled out in the absence of experimental data on how the counter ion (dimethyl oxazolidine) affects the irritation/corrosion potential of the chemical.

Dimethyl oxazolidine is classified as hazardous in the HCIS (SWA n.d.) as 'Skin irritation - Category 2'. The available data supports this classification. In a GLP compliant skin irritation/corrosion study, New Zealand White rabbits (6/dose) were exposed to 0.5 mL (82% w/w) of dimethyl oxazolidine on 1 square inch of skin for 4, 24, and 48 hours. After administration, all animals showed erythema and five animals showed oedema. After 48 hours four animals still showed from mild to strong erythema, but no tissue destruction of the treated skin sites was observed (REACH n.d.-a)

LAS with a variety of counter ions are classified as hazardous in the HCIS (SWA n.d.) as 'Skin irritation - Category 2'. The available data support this classification:

- Sodium (C10-13)-alkylbenzene sulfonate (47%) (CAS No. 68411-30-3) was considered severely irritating in a non-GLP compliant skin irritation/corrosion study similar OECD TG 404 (NICNAS 2014).
- Benzenesulfonic acid, mono-C10-13-alkyl derivs., compds. with ethanolamine were considered severely irritating in a non-guideline study (CAS No. 85480-55-3) (NICNAS 2014).
- Benzenesulfonic acid, dodecyl-, compound with 2-propanamine (1:1) (CAS No. 26264-05-1) was considered irritating in a GLP compliant in vitro skin irritation study conducted in accordance with OECD TG 439 (AICIS 2022).
- Benzenesulfonic acid, dodecyl-, compound with 2-propanamine (1:1) (CAS No. 26264- 05-1) was considered non-corrosive in a GLP compliant in vitro skin corrosion assay conducted in accordance with OECD TG 431 (AICIS 2022).
- Benzenesulfonic acid, dodecyl-, compound with 2-propanamine (1:1) (CAS No. 26264-05-1) was considered irritating in a non-guideline study in rabbits (AICIS 2022; NICNAS 2014).
- Benzenesulfonic acid, dodecyl-, compound with 2,2',2''-nitrilotris[ethanol] (1:1) (CAS No. 27323-41-7) was considered irritating in a non-guideline study in rabbits (AICIS 2022).

In solution, the irritation potential of the chemical will depend on the levels of dodecylbenzenesulfonic acid and formaldehyde. Linear alkylbenzene sulfonic acids (LASA) are corrosive to skin (AICIS 2022) and formaldehyde solutions are regarded as corrosive (NICNAS 2006).

Eye irritation

No data are available for the chemical.

Based on data for LAS and dimethyl oxazolidine the chemical (in pure form) is expected to cause serious eye damage.

A number of LAS with a variety of counter ions are classified as hazardous in the HCIS (SWA n.d.) as 'Eye damage – Category 1'. In several guideline studies in rabbits, LAS were not irritating to the eye at concentrations up to 1%, moderately irritating at 5% and severely irritating at 47–50% (NICNAS 2014).

Dimethyl oxazolidine is classified as hazardous in the HCIS (SWA n.d.) as 'Eye Irritation – Category 2A'.

In two eye irritation studies conducted in accordance with DFA guidelines, dimethyl oxazolidine was instilled into 1 eye each of 6 rabbits. The eyes were washed out after 1 min and observed at 24, 48 and 72 hrs. The following mean scores were reported as a range at 24, 48 and 72 hrs: corneal opacity 2–4, iritis 1–2, conjunctival redness 1–3 and chemosis 2–3. Adverse reactions were detected in all treated eyes and the reactions became more progressively severe at the time of the later observations. Reversibility of effects were not reported (REACH n.d.-a).

In solution, the irritation potential of the chemical will depend on the levels of dodecylbenzenesulfonic acid and formaldehyde. Linear alkylbenzene sulfonic acids caused severe eye damage in rabbits (AICIS 2022). As formaldehyde is not likely to be sufficiently volatile from end use products containing the chemical sensory irritation from formaldehyde vapour release is not expected. During formulation of the products, formaldehyde gas could be present. If the solution is applied directly to the eye, irritation could occur due to the severe irritancy of formaldehyde (NICNAS 2006).

Sensitisation

Skin sensitisation

The chemical is expected to release formaldehyde. Formaldehyde is a strong sensitiser (NICNAS 2006). Therefore, the chemical is expected to be a skin sensitiser, warranting hazard classification.

Dimethyl oxazolidine is classified as hazardous in the HCIS (SWA n.d.) as 'Skin sensitisation – Category 1'. The classification was based on the release of formaldehyde (NICNAS 2018). Dimethyl oxazolidine was negative in a Buehler assay (10 animals, induction concentration approximately 4% the chemical, challenge concentration <1.5%). Mixed results were observed in non-guideline studies (REACH n.d.-a).

While in vitro and in silico studies suggest that some LAS may have skin sensitisation potential, the weight of evidence indicate that LAS are unlikely to be potent skin sensitisers (AICIS 2022).

Respiratory sensitisation

No data are available for the chemical.

Formaldehyde is not classified as a respiratory sensitiser (NICNAS 2006).

Repeat dose toxicity

No data are available for the chemical.

There are no data available for dimethyl oxazolidine. Based on the available data for formaldehyde and LAS, the chemical is not expected to cause serious systemic health effects following repeated oral and dermal exposures.

Based on the weight of evidence from the repeated dose toxicity studies LAS and LASA do not cause serious damage to health by prolonged exposure (AICIS 2022). In oral gavage, dietary and drinking water studies in rats and mice ranging between 28 days and 2 years, lowest observed adverse effect levels (LOAELs) of 115–750 mg/kg bw/day were reported. The no observed adverse effect levels (NOAELs) ranged from 40 to 250 mg/kg bw/day. Reported adverse effects include reduced body weight gain, diarrhoea, increases in relative liver weight, differences in enzymatic and serum-biochemical parameters, and mild degeneration and desquamation of the tubular epithelium in the kidneys. In the study reporting the lowest LOAEL, LAS was fed daily to Wistar rats for six months at concentrations from 0.07 to 1.8%.

In available dermal repeated dose toxicity data with LAS, effects were attributed to local irritant effects. No inhalation data are available for LAS (AICIS 2022).

Limited data are available for dimethyl oxazolidine. In sub chronic dermal toxicity studies, observed effects were mostly limited to local effects. A NOEL of 100 mg/kg bw/day was reported in one study (AICIS 2018).

No systemic toxicity was observed following repeated exposure to formaldehyde in animals and humans (NICNAS 2006).

Genotoxicity

No data are available for the chemical.

Based on the available data for both salt components, the chemical is not considered to be genotoxic. While dimethyl oxazolidine was positive a number of the in vitro studies, the positive results were not confirmed in equivalent in vivo studies.

In vitro

Negative results were reported for LAS and LASA in several in vitro assays including bacterial reverse mutation assays (OECD TG 471), chromosome aberration study (OECD TG 473) in Chinese hamster ovary (CHO) cells, mammalian cell gene mutation studies (OECD TG 476) in CHO cell and a sister chromatid exchange (SEC) assay (AICIS 2022).

Positive results have been reported for dimethyl oxazolidine in gene mutation assays in mouse lymphoma cells. Positive results were also reported in a chromosomal aberration test using Chinese hamster ovary cells (NICNAS 1998).

- In a bacterial reverse mutation assay (OECD TG 471) dimethyl oxazolidine (CAS 51200-87-4) was tested on *Salmonella typhimurium* strain TA 100, TA1535, TA1537, TA98 and *Escherichia coli* strain WP2 uvrA both in the presence and absence of metabolic activation at concentrations up to 1250 ug/plate. The chemical was reported to be mutagenic in *S. typhimurium* TA98 and TA100 in the presence of metabolic activation (REACH n.d.-a).

In vivo

- In a Mammalian erythrocyte micronucleus induction test (OECD TG474) on CD-1 mice (5/sex/dose) bone marrow cells, micronuclei were not induced in bone marrow cells of male treated intraperitoneally with dimethyl oxazolidine with a single dose of 500 mg/kg bw (REACH n.d.-a).
- In a mammalian cell study (OECD TG489) on 8 male Sprague-Dawley rats' testicular cells, a significant increase in the elution rate of testicular DNA was not observed at the maximum tolerated dose of 50 mg/kg bw (REACH n.d.-a).
- In an unscheduled DNA synthesis assay (OECD TG486) on male Fischer 344 rats (4/dose) hepatocytes, no compound related increase in net nuclear grain counts were observed (REACH n.d.-a).
- LAS or LASA did not induce clastogenic effects in cytogenetic assays in rats and mice, in a dominant lethal assay in rats, and in a micronucleus test in mice (AICIS 2022).

In silico

- The chemical does not have a structural alert for protein binding (NOTE: DNA binding for mutagenicity endpoint) based on the mechanistic (and endpoint-specific) profiling functionality of the OECD QSAR Toolbox version 4.2 (OECD 2022). The chemical is predicted to be non-mutagenic (71.4% in domain) using OASIS–TIMES in vitro Ames mutagenicity (Optimised Approach based on Structural Indices Set–Tissue Metabolism Simulator; version 2.28) and the expert rule-based system, DEREK (Deductive Estimation of Risk from Existing Knowledge) Nexus (version 2.2), (Lhasa Limited).

Carcinogenicity

No data are available for the chemical.

Based on the available data for both salt component, the chemical is not considered to be carcinogenic.

No data are available for dimethyl oxazolidine. While formaldehyde is classified as hazardous with hazard category 'Carcinogenicity—Category 1B' and hazard statement 'May cause cancer by inhalation' (H350i) in the HCIS (SWA n.d.), this applies to inhaled formaldehyde, at high concentrations (NICNAS 2006). Formaldehyde is not likely to be sufficiently volatile from end use products containing the chemical. During formulation of the products, formaldehyde gas could be present.

In four 2-year carcinogenicity studies, LAS was administered to rats at concentrations up to 300 mg/kg bw/day in diet or 200 mg/kg bw/day in drinking water. No gross or histopathological evidence of tumorigenesis or carcinogenic effects were reported in these studies (AICIS 2022).

Reproductive and development toxicity

No data are available for the chemical.

Based on the available data for the salts counter ions and the hydrolysis product formaldehyde, the chemical is not expected to cause specific adverse effects on development and or fertility.

There was no evidence of reproductive, fertility or developmental toxicity effects in multi-generation studies with LAS. Adverse effects on development were only observed at maternally toxic doses in multiple developmental and teratogenicity toxicity studies in rats, mice and rabbits.

Limited data are available for dimethyl oxazolidine. No developmental effects were observed in a dermal developmental study in rabbits (NICNAS 2018). Formaldehyde is not considered to be a reproductive or developmental toxin (NICNAS 2006).

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