



Australian Government

Department of Health and Aged Care

Australian Industrial Chemicals Introduction Scheme

Alkoxysilanes substituted with 2-ethoxyethanol

Evaluation statement

25 September 2023

Draft

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AICIS evaluation statement

Subject of the evaluation

Alkoxysilanes substituted with 2-ethoxyethanol

Chemicals in this evaluation

Name	CAS registry number
Silicic acid (H ₄ SiO ₄), tetrakis(2-ethoxyethyl) ester	18407-94-8
3,6,8,11-tetraoxa-7-silatridecane, 7-(2-ethoxyethoxy)-7-ethyl-	61667-41-2

Reason for the evaluation

Evaluation Selection Analysis indicated a potential human health risk.

Parameters of evaluation

These chemicals are listed on the Australian Inventory of Industrial Chemicals (the Inventory). This evaluation statement includes a human health risk assessment for all identified industrial uses of these chemicals.

These chemicals have been assessed as a group as they are structurally related alkoxysilanes that have a common metabolite, 2-ethoxyethanol (CAS No. 110-80-5). These chemicals are expected to have similar use patterns, similar toxicity and bioavailability.

Summary of evaluation

Summary of introduction, use and end use

There is currently no specific information about the introduction, use and end use of these chemicals in Australia and limited international information are available.

Based on international use information for structurally related alkoxysilanes, these chemicals are expected to have site limited uses as an intermediate and commercial uses in paints, coatings, adhesives and sealants.

Human health

Summary of health hazards

No data are available for these chemicals. Data from other chemicals are used as read across to infer the toxicity of these chemicals as follows:

- data from the structurally related alkoxysilanes for acute and local effects

- data from the common metabolite, 2-ethoxyethanol (CAS No. 110-80-5) for systemic toxicity.

Based on the available data, these chemicals are likely to:

- have low acute oral and dermal toxicity
- be slightly irritating to the eyes
- not cause skin sensitisation
- not have genotoxic potential.

Based on the available data, these chemicals are expected to cause specific adverse effects on fertility and development. The metabolite, 2-ethoxyethanol, causes adverse effects to the male reproductive system and has been shown to adversely affect reproductive capability and capacity in both sexes for at least one generation. In addition, studies with the metabolite in rabbits, rats and mice using the oral, dermal and inhalation route of exposure consistently demonstrated that 2-ethoxyethanol adversely affects embryonic and foetal development. Similar adverse effects on fertility and development have been observed with a structurally related alkoxysilane, tris(2-methoxyethoxy)vinylsilane (CAS No. 1067-53-4). These chemicals are also likely to cause effects on the haematopoietic systems; however, the doses at which effects are likely to occur are not sufficient to warrant classification.

Based on in silico predictions and in vivo data for structurally related alkoxysilane, tetrakis(2-butoxyethyl) orthosilicate (CAS No. 18765-38-3), these chemicals may be moderately irritating to the skin. Tetrakis(2-butoxyethyl) orthosilicate is reported to cause moderate skin irritation in rabbits (mean erythema score was >2.3, in 2 out of 3 animals) in an in vivo skin irritation study in rabbits.

While no inhalation data are available, both chemicals are predicted to have low volatility.

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

Hazard classifications relevant for worker health and safety

These chemicals satisfy the criteria for classification according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (UNECE 2017) for hazard classes relevant for work health and safety, as follows. This evaluation does not consider classification of physical hazards and environmental hazards.

Health hazards	Hazard category	Hazard statement
Skin corrosion/irritation	Skin Irrit. 2	H315: Causes skin irritation
Reproductive toxicity	Repr. 1B	H360FD: May damage fertility. May damage the unborn child.

Summary of health risk

Public

Based on the available use information, it is unlikely that the public will be exposed to these chemicals. The public could come into contact with articles or coated surfaces containing these chemicals in reacted form. It is expected that these chemicals will be bound within

articles and coated surfaces, and hence will not be bioavailable. Therefore, there are no identified risks to the public that require risk management.

Workers

During product formulation and packaging, incidental dermal, ocular and inhalation exposure may occur, particularly where manual or open processes are used. These processes include transferring, blending, quality control, cleaning and maintaining of equipment. During end use, worker exposure to these chemicals at lower concentrations may occur while using formulated products containing these chemicals. The level and route of exposure will vary depending on the method of application, control measures and work practices.

Given the critical systemic long term health effects, these chemicals may pose a risk to workers. Control measures to minimise dermal and inhalation exposure are needed to manage the risk to workers (see **Proposed means for managing risks** 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 report includes recommended hazard classifications and 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 Model Work Health and Safety Regulations.

Control measures that can be implemented to manage the risk arising from exposure to these chemicals include, but are not limited to:

- using closed systems or isolating operations
- minimising manual processes or conducting work tasks through automated processes
- adopting work procedures that minimise splashes and spills
- cleaning equipment and work areas regularly
- using personal protective equipment that is designed, constructed, and operated to ensure that workers do not come into contact with these chemicals.

Measures required to eliminate or manage risk arising from storing, handling, and using a hazardous chemical depend on the physical form and the manner in which 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 conclusions of this evaluation are based on the information described in this statement.

Considering the proposed means of managing risks, the Executive Director proposes to be satisfied that the identified human health risks can be managed within existing risk management frameworks. This is provided that:

- all requirements are met under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory, and
- the proposed means of managing the risks identified during this evaluation are implemented.

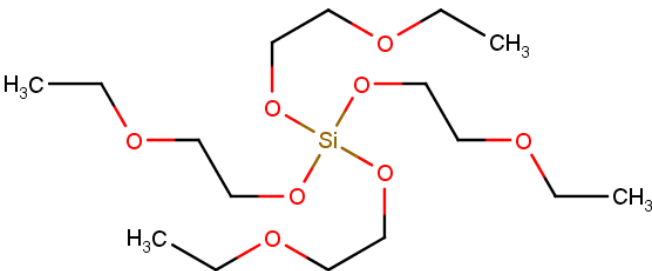
Note: Obligations to report additional information about hazards under *Section 100 of the Industrial Chemicals Act 2019* apply.

Supporting information

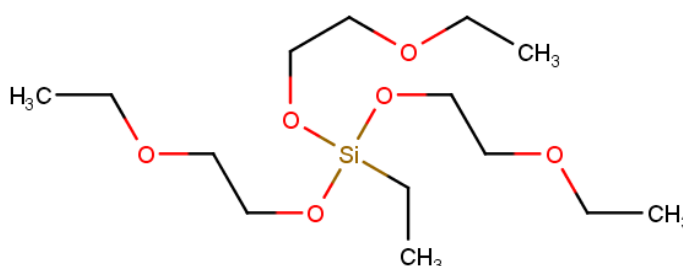
Grouping rationale

This chemical group consists of short chain linear siloxanes containing a single Si-O moiety substituted with three to four 2-ethoxyethoxy groups. Chemicals in this group are expected to be metabolised in the body to 2-ethoxyethanol (CAS No. 110-80-5) and their corresponding silanol metabolites. Systemic toxicity associated with these chemicals is expected to be primarily driven by the 2-ethoxyethanol moiety. While the lower molecular weight silanol metabolites have the potential to penetrate cellular membranes and bioaccumulate, there is limited evidence in literature of any systemic toxicity specifically attributed to this class of silanols (Mojsiewicz-Pieńkowska et al. 2016).

Chemical identity

Chemical name	Silicic acid (H ₄ SiO ₄), tetrakis(2-ethoxyethyl) ester
CAS No.	18407-94-8
Synonyms	tetrakis(2-ethoxyethyl) orthosilicate tetrakis(2-ethoxyethyl) silicate
Molecular formula	C ₁₆ H ₃₆ O ₈ Si
Molecular weight (g/mol)	384.54
SMILES	<chem>CCOCCO[Si](OCCOCC)(OCCOCC)OCCOCC</chem>
Chemical description	-
Structural formula	

Chemical name	3,6,8,11-Tetraoxa-7-silatridecane, 7-(2-ethoxyethoxy)-7-ethyl-
CAS No.	61667-41-2
Synonyms	7-(2-ethoxyethoxy)-7-ethyl-3,6,8,11-tetraoxa-7-silatridecane tris(2-ethoxyethoxy)-ethylsilane
Molecular formula	C ₁₄ H ₃₂ O ₆ Si
Molecular weight (g/mol)	324.48
SMILES	CCOCCO[Si](CC)(OCCOCC)OCCOCC
Chemical description	-
Structural formula:	



Relevant physical and chemical properties

Based on physical and chemical properties calculated using standard quantitative structure property relationships (QSPR) (US EPA 2017) these chemicals are soluble in water and are expected to rapidly hydrolyse. The predicted log Kow values are -1 for tetrakis(2-ethoxyethyl) orthosilicate (CAS No. 18407-94-8) and 0.5 for tris(2-ethoxyethoxy)-ethylsilane (CAS No. 61667-41-2). These chemicals are predicted to have low volatility (estimated vapour pressures of 0.002-0.007 Pa).

Introduction and use

Australia

No specific Australian information about the introduction, use and end use of these chemicals in Australia have been identified.

International

Limited information on the introduction, use and end use of these chemicals was identified. Tetrakis(2-ethoxyethyl) orthosilicate (CAS No. 18407-94-8) is reported to be active under *Toxic Substances Control Act (TSCA)*. Based on available Safety Data Sheets (SDSs), the chemical has reported use as an intermediate. No information has been identified for tris(2-ethoxyethoxy)-ethylsilane (CAS No. 61667-41-2).

Based on information for structurally related alkoxy silanes: tris(2-methoxyethoxy)vinylsilane (CAS No. 1067-53-4) and tetrakis(2-butoxyethyl) orthosilicate (CAS No. 18765-38-3), these chemicals are likely to have commercial uses in paints, coatings, adhesives and sealants; and site limited uses as an intermediate (AICIS 2022; REACH n.d.).

Given the limited data available for these chemicals, consumer uses of these chemicals are considered unlikely. No cosmetic uses for these chemicals were reported.

Existing Australian regulatory controls

AICIS

No specific controls are currently available for these chemicals.

Public

No specific controls are currently available for these chemicals.

Workers

These chemicals are not listed on the HCIS (Safe Work Australia, SWA).

No exposure standards are available for these chemicals in Australia (SWA).

International regulatory status

No specific controls have been identified for these chemicals.

Health hazard information

No data are available for these chemicals. Data for other chemicals have been used to infer the toxicity of these chemicals.

For acute and local effects, data from the following structurally related alkoxy silanes, with similar physical and chemical properties to these chemicals, have been used:

- tetrakis(2-butoxyethyl) orthosilicate (CAS No. 18765-38-3) is a silicic acid substituted with four 2-butoxyethanol groups
- tris(2-methoxyethoxy)vinylsilane (CAS No. 1067-53-4) is an organoalkoxy silane substituted with 2-methoxyethanol. The vinyl functionality does not appear to significantly impact local toxicity (AICIS 2022).

For systemic toxicity, data for the common metabolite, 2-ethoxyethanol (CAS No. 110-80-5) have been used. Data for tris(2-methoxyethoxy)vinylsilane (CAS No. 1067-53-4) have also been used as supporting information. Although this has a different metabolite, the metabolites, 2-methoxyethanol (CAS No. 109-86-4) and 2-ethoxyethanol have a similar toxicological profile (NICNAS 2014).

Toxicokinetics

No specific toxicokinetic studies are available for these chemicals. They are expected to be bioavailable following oral, dermal and inhalation exposure based on their molecular weights (224–384 g/mol) and predicted log Kow values (3.35). Once absorbed, these chemicals are expected to be hydrolysed and the products would likely be widely distributed in the blood.

In in vitro guideline hydrolysis studies (OECD Test Guideline (TG) 111) compliant with Good Laboratory -Practice (GLP) principles, the structurally related alkoxy silanes: tris(2-methoxyethoxy)vinylsilane (CAS No. 1067-53-4) and tetrakis(2-butoxyethyl) orthosilicate (CAS No. 18765-38-3) rapidly hydrolysed at physiological pH values to form the relevant alkoxyethanol (AICIS 2022, REACH). Therefore, these chemicals are expected to undergo rapid hydrolysis to form 2-ethoxyethanol (where it is expected to be subsequently oxidised to ethoxyacetic acid) (NICNAS 2014).

Acute toxicity

Oral

No data are available for these chemicals. Based on reported oral median lethal dose (LD50) values of >2000 mg/kg bw for structurally related alkoxy silanes: tris(2-methoxyethoxy)vinylsilane (CAS No. 1067-53-4) and tetrakis(2-butoxyethyl) orthosilicate (CAS No. 18765-38-3) (AICIS 2022; REACH n.d.) are expected to have low acute oral toxicity.

Dermal

No data are available for these chemicals. Based on reported dermal LD50 values of >2000 mg/kg bw for structurally related alkoxy silanes: tris(2-methoxyethoxy)vinylsilane (CAS No. 1067-53-4) and tetrakis(2-butoxyethyl) orthosilicate (CAS No. 18765-38-3), (AICIS 2022; REACH n.d.) are expected to have low dermal acute toxicity

Inhalation

No data are available for these chemicals.

Corrosion/Irritation

Skin irritation

No data are available for these chemicals. Based on in silico predictions and in vivo data for structurally related alkoxy silane, tetrakis(2-butoxyethyl) orthosilicate (CAS No. 18765-38-3), chemicals in this group may be moderately irritating to the skin. A hazard classification is warranted (see **Hazard classifications relevant for worker health and safety** section).

In vivo

In a GLP compliant skin irritation study conducted in accordance with OECD TG 404, 3 small White Russian rabbits were treated with the structurally related chemical, tetrakis(2-butoxyethyl) orthosilicate (CAS No. 18765-38-3), for 4 hours under semi-occlusive conditions. In 2 out of 3 animals, the following mean scores were reported for observations at 24, 48 and 72 hours: 3.33 for erythema and 1.67 for oedema respectively (maximum score of 4). All treatment related effects were reported to be reversed by day 10 of the study (REACH n.d.).

The structurally related chemical, tris(2-methoxyethoxy)vinylsilane (CAS No. 1067-53-4) was reported to be slightly irritating to the skin of rabbits in a GLP compliant, guideline acute dermal irritation study (OECD TG 404) (AICIS 2022).

In silico

OASIS TIMES (optimized approach based on structural indices set–tissue metabolism simulator) (OASIS LMC n.d) was utilised to estimate the skin irritation potential of these chemicals. A structural alert for skin irritation, silicon ethers, was reported for tris(2-ethoxyethoxy)-ethylsilane (CAS No. 61667-41-2). The chemical was predicted (within applicability domain) to be irritating to skin. No structural alert was reported for tetrakis(2-ethoxyethyl) orthosilicate (CAS No. 18407-94-8).

Eye irritation

No data are available for these chemicals. Based on data for structurally related alkoxysilanes: tris(2-methoxyethoxy)vinylsilane (CAS No. 1067-53-4) and tetrakis(2-butoxyethyl) orthosilicate (CAS No. 18765-38-3), chemicals in this group may be at most, slightly irritating to the eyes.

In a GLP compliant eye irritation study conducted in accordance with OECD TG 405, tetrakis(2-butoxyethyl) orthosilicate (CAS No. 18765-38-3) was instilled into 1 eye each of 3 small White Russian rabbits. Two of the rabbits had conjunctival chemosis (grade 1) and all 3 had conjunctival redness (grade 1 and 2), which had reversed by 24 hours. Mean scores (for all 3 animals) based on observations at 24, 48, 72 hours were 0 for corneal opacity, iritis, conjunctival redness and chemosis (REACH n.d.).

Tris(2-methoxyethoxy)vinylsilane (CAS No. 1067-53-4) was reported to be slightly irritating to the eyes of rabbits in a GLP compliant, guideline acute dermal irritation study (OECD TG 405) (AICIS 2022).

In silico

OASIS TIMES (OASIS LMC n.d) was utilised to estimate the eye irritation potential of these chemicals. In silico predictions were not within the applicability domain of the model.

Sensitisation

Skin sensitisation

No data are available for these chemicals. Based on data for structurally related alkoxysilanes: tris(2-methoxyethoxy)vinylsilane (CAS No. 1067-53-4) and

tetrakis(2-butoxyethyl) orthosilicate (CAS No. 18765-38-3), chemicals in this group are not likely to be skin sensitisers.

In a GLP compliant in vivo skin sensitisation study conducted similar to OECD TG 406 (Buehler test), 10 Dunkin Hartley guinea pigs were induced with tetrakis(2-butoxyethyl) orthosilicate (CAS No. 18765-38-3). There were 3, 6 hour induction phases (using 100% of the chemical in phases 1 and 2; and 50% of the chemical in corn oil in phase 3). These animals were then challenged with 50% of the chemical in corn oil. During induction phases, mild irritation was reported in some animals. Following challenge, no treated animals showed skin reactions. The chemical was reported to be non-sensitising in this study (REACH n.d.).

Tris(2-methoxyethoxy)vinylsilane (CAS No. 1067-53-4) was reported to be negative for skin sensitisation in Dunkin Hartley guinea pigs based on a GLP compliant, in vivo guideline study for skin sensitisation (OECD TG 406, Buehler test) (AICIS 2022).

In silico

No structural alerts for skin sensitisation were identified for the chemicals in this group using OECD QSAR Toolbox (OECD 2023), or the expert rule based system, DEREK (Deductive Estimation of Risk from Existing Knowledge) Nexus (Lhasa Limited n.d.). However, when autoxidation or skin metabolism was simulated in OECD Toolbox, mechanistic alerts were reported for protein binding and skin sensitisation for both chemicals. Predictions using OASIS TIMES were not within the applicability domain of the models.

Repeat dose toxicity

No data are available for these chemicals. Based on data for the common metabolite, 2-ethoxyethanol (CAS No. 110-80-5), repeated exposure to these chemicals through all routes is likely to cause effects on the testes and haematopoietic systems. The doses at which effects are likely to occur are not sufficient to warrant classification.

Several repeated dose toxicity studies on 2-ethoxyethanol are available, with investigations performed in rats, mice, rabbits, and dogs. Effects in the haematopoietic system included mild haemolytic anaemia and corresponding haemosiderin accumulation and isolated haematopoietic foci in the spleen. Effects in the male reproductive system included testicular atrophy, degeneration of testicular tubules decrease in sperm counts and motility, and an increase in the number of abnormal sperm cells. The lowest observed adverse effect level (LOAEL) was 186 mg/kg bw/day estimated in a 13 week rat study (no observed adverse effect level (NOAEL) 93 mg/kg bw/day). Through the inhalation route, the lowest adverse effect concentration (LOAEC) was reported to be 400 ppm (equivalent to 1480 mg/m³) in rabbits (ECHA 2011; NICNAS 2014).

Based on the respective molecular weights and assuming these chemicals are fully hydrolysed, the estimated NOAEL levels would be approximately double. Therefore, it is unlikely that effects would be observed at sufficient concentrations to warrant classification for specific target organ toxicity following repeated exposure (STOT-RE).

In a GLP compliant, guideline study in CrI:CD(SD) rats conducted similarly to OECD TG 422 with tris(2-methoxyethoxy)vinylsilane (CAS No. 1067-53-4), adverse effects on male reproductive organs, thymus and haematopoietic system were reported (AICIS 2022). The data support that alkoxysilanes which metabolise to 2-alkoxyethanols have similar systemic effects as their metabolite.

Genotoxicity

No data are available for these chemicals. Based on the available in vitro data on structurally related alkoxysilanes: tris(2-methoxyethoxy)vinylsilane (CAS No. 1067-53-4), these chemicals are unlikely to have genotoxic potential.

The metabolite, 2-ethoxyethanol is considered to have, at most, weak genotoxic potential (NICNAS 2014).

Tris(2-methoxyethoxy)vinylsilane (CAS No. 1067-53-4) was reported to be non-genotoxic in several in vitro studies (AICIS 2022).

In silico

There were no structural alerts for in vitro mutagenicity (Ames test) using DEREK Nexus, and OECD QSAR Toolbox (Lhasa Limited n.d., OECD 2023). These chemicals were predicted to be in vitro Ames negative in OASIS TIMES (OASIS LMC n.d.). The prediction for tetrakis(2-ethoxyethyl) orthosilicate (CAS No. 18407-94-8) was within the applicability domain of the model. The prediction for tris(2-ethoxyethoxy)-ethylsilane (CAS No. 61667-41-2) was out of the applicability domain.

Carcinogenicity

No data are available for these chemicals or the structurally related alkoxysilane tris(2-methoxyethoxy)vinylsilane (CAS No. 1067-53-4).

There is no evidence of carcinogenicity in the available long term studies with the metabolite, 2-ethoxyethanol (CAS No. 110-80-5) in rats and mice, although the studies had limitations compared with guideline studies (NICNAS 2014).

Reproductive and development toxicity

No data are available for these chemicals. Based on data for the common metabolite, 2-ethoxyethanol (CAS No. 110-80-5) and structurally related chemical, tris(2-methoxyethoxy)vinylsilane (CAS No. 1067-53-4), these chemicals are expected to cause specific adverse effects on fertility and development. A hazard classification is warranted (see **Hazard classifications relevant for worker health and safety** section).

Adverse effects to the male reproductive system have been reported in several species following exposure to metabolite, 2-ethoxyethanol (CAS No. 110-80-5) by all routes of exposure. The metabolite, 2-ethoxyethanol has been shown to adversely affect reproductive capability and capacity in both sexes for at least one generation (ECHA 2011; NICNAS 2014).

In additional studies with rabbits, rats and mice using the inhalation, oral and dermal route of exposure, consistently demonstrated that 2-ethoxyethanol adversely affects embryonic and foetal development. Effects observed include decreased number of litters, reduced foetal bodyweight, reduced pup viability and increased incidence of foetal malformations. Significantly increased incidences of these developmental effects were observed at dose levels without specific maternally toxic effects (ECHA 2011; NICNAS 2014).

Human data from several epidemiological studies may indicate an association between exposure to metabolite, 2-ethoxyethanol and impairment of reproduction in humans (both

sexes). Whilst confounding factors such as exposure to other chemicals could not be completely ruled out with some of these observations, the observations are consistent with those in animals (ECHA 2011; NICNAS 2014).

In a GLP compliant, guideline study in CrI:CD(SD) rats conducted similarly to OECD TG 422 with tris(2-methoxyethoxy)vinylsilane (CAS No. 1067-53-4), adverse effects on reproduction and development were reported (AICIS 2022). The data support that alkoxy silanes which metabolise to 2-alkoxyethanols have similar effects on reproduction and development as their metabolite.

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