

# Zinc, bis(hydroxymethanesulfinato-OS,O1)-, (T-4)-: Human health tier II assessment

01 July 2016

**CAS Number: 24887-06-7**



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## 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](http://www.nicnas.gov.au)

### Disclaimer

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## Acronyms &amp; Abbreviations

## Chemical Identity

Synonyms	zinc formaldehyde sulfoxylate bis(hydroxymethanesulfinato-O,O')zinc zinc, bis(1-(hydroxy-kappaO)methanesulfinato-kappaO)-, (T-4)- Safolin Decroline
Structural Formula	 Structural formula of Zinc, bis(hydroxymethanesulfinato-O,S,O1)-, (T-4)-
Molecular Formula	C2H6O6S2Zn
Molecular Weight (g/mol)	255.585
Appearance and Odour (where available)	White crystalline powder with a pungent odour
SMILES	<chem>C(O)S(=O)O{-}.[Zn]{2+}.O{-}S(=O)CO</chem>

## Import, Manufacture and Use

## Australian

The chemical has reported site-limited use including as a reducing agent for discharge printing on polyester, nylon and other synthetic fibres (SDS).

## International

The following international uses have been identified through: Galleria Chemica; the Substances and Preparations in the Nordic countries (SPIN) database; the European Commission Cosmetic Ingredients and Substances (CosIng) database; the United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary and the United States US National Library of Medicine's Hazardous Substances Data Bank (HSDB).

The chemical has reported cosmetic use as a reducing agent.

The chemical has reported site-limited uses including:

- in the manufacture of textiles;
- in colour printing pastes;
- in the polymerisation of ethylenic compounds; and
- as a stripping and discharging agent for textiles, colourants and dyes.

The chemical has reported non-industrial uses, including as a bleaching agent for molasses and in the manufacture of arspenamines.

## Restrictions

## Australian

No known restrictions have been identified.

## International

The chemical is listed on the European Union (EU) Cosmetics Regulation Annex III—List of substances which cosmetic products must not contain except subject to the restrictions and conditions laid down (maximum concentration in ready for use preparations is 1 %) (Galleria Chemica).

## Existing Work Health and Safety Controls

### Hazard Classification

The chemical is not listed on the Hazardous Substances Information System (HSIS) (Safe Work Australia).

### Exposure Standards

#### Australian

No specific exposure standards are available.

#### International

No specific international exposure standards are available.

## Health Hazard Information

Zinc, bis(hydroxymethanesulfonato-OS,O1)-, (T-4)- (CAS No. 24887-06-7), also known as zinc formaldehyde sulfoxylate, has various industrial uses including in the textiles industry. Limited data are available for this chemical; however, as it is expected to dissociate in biological fluids, data will be read-across from soluble zinc salts, primarily zinc sulfate (CAS No. 7733-02-0), for the zinc cation and sodium hydroxymethanesulfinate (CAS No. 149-44-0), also called sodium formaldehyde sulfoxylate, for the formaldehyde sulfoxylate anion. Assessment of the chemical will take into account data for both ionic species using a weight-of-evidence approach.

Data for the zinc cation will be taken from a previously conducted NICNAS human health Tier II assessment for soluble zinc salts (NICNAS).

### Toxicokinetics

#### *Formaldehyde sulfoxylate anion*

The following toxicokinetic data relating to sodium formaldehyde sulfoxylate were generated in a study assessing its potential to reverse the effects of mercury poisoning in canines (REACH).

Digestive tract absorption was low following oral administration. Following intravenous injection, practically all of the chemical had disappeared from the blood within five hours. Due to the chemical's strong hydrophilicity, rapid distribution into blood, plasma and water-based biological fluids is expected.

No metabolites of sodium formaldehyde sulfoxylate were identified in the experiments with canines and it was found that the majority of the chemical (68 %) was excreted in urine within eight hours of intravenous administration. Given the hydrophilicity of the chemical, metabolic conversion is not likely to be required for excretion (REACH).

#### *Zinc cation*

Absorption of zinc from oral exposure has been observed to vary between 8–80 % (EU RAR, 2004). Dermal absorption of zinc is thought to be minimal. In one study, acidic solutions of zinc chloride, applied to the shaven, intact dorsal skin of Sprague Dawley (SD) rats resulted in 3.6–6.1 % absorption. Less acidic solutions containing zinc chloride resulted in a dermal absorption of less than 2 % (Hallmans & Liden, 1978).

There are no quantitative data to support the absorption of zinc cations through intact skin in humans. However, absorption has been reported through damaged or burned skin.

Zinc is distributed throughout all tissues in humans and is a cofactor in over 300 enzyme systems. The highest concentrations of zinc in human tissues are found in bone and muscle (60 and 30 %, respectively), followed by the prostate, liver and kidney. A similar pattern of distribution has been demonstrated in animals (Wastney et al., 2014).

Zinc does not undergo metabolism and is typically found in the body as a divalent cation, complexed with albumin or other serum proteins (EPA IRIS, 2005).

In humans, approximately 70–80 % of ingested zinc is excreted via the faeces (5–10 mg/day depending on the concentration of dietary zinc). Zinc is also excreted via the urine, sweat, saliva, breast milk and may also be excreted via hair (EU RAR, 2004).

## Acute Toxicity

### Oral

The chemical is expected to have moderate acute toxicity based on data for the zinc cation. The median lethal dose (LD50) in rats for zinc-containing compounds ranges from 920 to 2949 mg/kg bodyweight (bw). Hazard classification is recommended

Sodium formaldehyde sulfoxylate was assessed in an oral acute toxicity study in female SD rats (six animals/group), according to the Organisation for Economic Co-operation and Development (OECD) Test Guideline (TG) 423 (acute oral toxicity—acute toxic class method). Animals were administered the chemical at a single dose of 2000 mg/kg bw. No mortalities occurred during the study and no clinical signs related to dosing were observed in any animal. No body weight changes were observed and macroscopic pathological evaluations revealed no chemical-related effects. On the basis of these findings, an oral LD50 of >2000 mg/kg bw was determined.

Zinc sulfate and zinc sulfate heptahydrate (CAS No. 7446-20-0) are classified as hazardous with the risk phrase 'Harmful if swallowed' (Xn; R22) in HSIS (Safe Work Australia).

### Dermal

The chemical is expected to have low acute toxicity based on results from animal tests following dermal exposure. The LD50 in rats is expected to be >2000 mg/kg bw.

In a dermal acute toxicity study conducted according to OECD TG 402 (acute dermal toxicity), sodium formaldehyde sulfoxylate was applied to the intact skin of SD rats (five animals/sex/dose). Animals received a single dose applied to their skin at 2000 mg/kg bw. No mortalities occurred during the study and no local cutaneous, nor systemic evidence of toxicity was observed. No changes in body weight gain was reported and clinical and pathological evaluations of animals did not reveal any indication of toxicity. On the basis of these results, an LD50 of >2000 mg/kg bw was determined under these conditions (REACH).

Zinc sulfate had low acute toxicity in animal tests following dermal exposure (NICNAS).

### Inhalation

The chemical is expected to have low acute inhalation toxicity based on the limited available data. No hazard classification is recommended.

No data for acute inhalation toxicity are available for the formaldehyde sulfoxylate anion.

Zinc sulfate had low acute toxicity in well-documented studies with hamsters and dogs with no mortalities or toxic effects observed following inhalational exposure (NICNAS; REACH).

## Corrosion / Irritation

### Skin Irritation

The chemical is not expected to cause dermal irritation. No hazard classification is recommended.

Sodium formaldehyde sulfoxylate was assessed for dermal irritation in an acute dermal toxicity study conducted according to OECD TG 402 (acute dermal toxicity). The chemical was applied to the intact skin of SD rats (five/sex/dose) at a single dose of 2000 mg/kg bw and left for 25 hours under occlusive conditions. No mortalities occurred during the study and no evidence of irritation was observed at the site of application. On the basis of these findings, the chemical was not considered to be a dermal irritant (REACH).

Zinc sulfate produced no skin irritation in a study with New Zealand White rabbits, conducted according to OECD TG 404 (acute dermal irritation/corrosion) (NICNAS).

### Eye Irritation

The zinc cation is likely to cause ocular irritation given the findings of a study conducted in accordance with OECD TG 405. While the formaldehyde sulfoxylate anion is not expected to be an ocular irritant, hazard classification is recommended.

Sodium formaldehyde sulfoxylate was assessed for ocular irritation in a study conducted according to OECD TG 405 (acute eye irritation/corrosion). Three male New Zealand White rabbits had 0.1 g of powderised test chemical instilled into one eye. Animals were observed for signs of irritation at one, 24, 48, 72 and 96 hours after administration. No animals died during the study and no evidence of systemic toxicity was observed. Slight conjunctival redness was observed in two animals up to 24 hours and in one animal up to 72 hours after instillation. Some conjunctival swelling was also observed in

three animals. No corneal or iridial effects were observed in any animal at any time point. The grades attributed to these lesions (in accordance with OECD TG 405) were insufficient to warrant classification of sodium formaldehyde sulfoxylate as an ocular irritant (REACH).

Zinc sulfate caused long-lasting conjunctival effects when tested according to OECD TG 405 (NICNAS).

## Sensitisation

### Skin Sensitisation

Zinc formaldehyde sulfoxylate is unlikely to be a skin sensitiser based on the results of studies conducted with the anionic and cationic portions of the compound.

Sodium formaldehyde sulfoxylate was assessed for skin sensitisation in a guinea pig maximisation test (GPMT) conducted according to OECD TG 406 (skin sensitisation) with female Dunkin-Hartley guinea pigs. On day one of the study, two animals were each intradermally injected with 0.1 mL of test chemical at concentrations ranging from 1.56 to 50 %. On day seven, the chemical was topically applied to the backs of two guinea pigs for 24 hours, at four different concentrations (10, 20, 40 or 80 %). On day 20, animals were again topically administered the chemical at 10, 20, 40 or 80 %. No macroscopic dermal reactions consistent with allergic inflammation were recorded after induction with the test chemical. On this basis, the chemical sodium formaldehyde sulfoxylate was not considered to be a skin sensitiser (REACH).

Zinc sulfate heptahydrate was not considered to be a skin sensitiser (NICNAS).

## Repeated Dose Toxicity

### Oral

Based on the available information, no hazard classification for repeated dose oral toxicity is recommended.

Sodium formaldehyde sulfoxylate was assessed in a combined repeat dose toxicity/reproductive and developmental toxicity study according to OECD TG 422 (combined repeated dose toxicity study with the reproduction/developmental toxicity screening test). The test substance was orally administered to Wistar rats of both sexes (10 animals/sex/group) at 100, 300 or 1000 mg/kg bw/day. Males were exposed for two weeks prior to and during mating and up to termination (for 30 days). Females were exposed for two weeks prior and during mating, during post-coitum and for at least four days of lactation (42 – 53 days). In the highest dose group, two females exhibited abnormal posturing and/or piloerection for three days during pregnancy and/or lactation. Decreased body weight gain and food consumption were also observed at this dose level. Several haematological and hepatic blood chemistry parameters were found to be abnormal at this dose in both sexes. Organ to body weight ratios were increased for liver, spleen, testes and epididymides in males and for liver, spleen, kidneys and adrenals in females in the highest dose group. Histopathological examination showed no abnormalities in the affected organs. No parental toxicity was observed at the 100 and 300 mg/kg bw/day groups. There were no treatment-related mortalities during the study, and there were no functional observations, macroscopic or microscopic observations in the parental generation. Based on these observations, a No Observed Adverse Effect Level (NOAEL) of 300 mg/kg bw/day was determined for parental toxicity (REACH).

Considering the no-observed-effect levels (NOELs) available from 90-day mouse and rat studies are greater than 100 mg/kg bw/day for zinc sulfate heptahydrate, and based on the treatment-related effects reported in various repeat dose toxicity studies, the zinc cation is not expected to cause serious damage to health from repeated oral exposure (NICNAS.)

### Dermal

No data are available.

### Inhalation

Based on the available information, no hazard classification for repeated dose inhalation toxicity is recommended.

No data are available for the formaldehyde sulfoxylate anion. Zinc sulfate was not considered to cause severe repeat dose inhalation toxicity (NICNAS).

## Genotoxicity

Based on the weight of evidence from the available in vitro and in vivo genotoxicity studies on the formaldehyde sulfoxylate anion, zinc formaldehyde sulfoxylate is likely to be genotoxic and warrants classification. The zinc cation was not considered to be genotoxic (NICNAS).

### *In vitro*

Sodium formaldehyde sulfoxylate was assessed in an Ames test conducted according to OECD TG 417 (bacterial reverse mutation assay). The chemical was tested for genotoxicity in *Salmonella typhimurium* strains TA 87, TA 98, TA 100, TA 102 and TA 1535 at concentrations up to 5047 µg/plate, for 48 hours. The chemical did not cause an increase in the number of revertant colonies in any of the strains tested, at any of the concentrations assessed in the presence or absence of metabolic activation. On the basis of these findings, the test chemical was not considered to be mutagenic (REACH).

Sodium formaldehyde sulfoxylate was assessed for its potential to induce gene mutations in mammalian cells according to OECD TG 476 (in vitro mammalian cell gene mutation test). The chemical was incubated with mouse lymphoma L5178Y cells at concentrations up to 10 mM with and without metabolic activation for 24 hours. The chemical was found to be clastogenic at concentrations greater than 9.2 mM. Therefore, under these test conditions, the chemical was considered to be clastogenic in mammalian cells (REACH).

#### ***In vivo***

Sodium formaldehyde sulfoxylate was assessed for genotoxicity in a micronucleus test conducted according to OECD TG 474 (mammalian erythrocyte micronucleus test). Male and female NMRI mice (10 animals/group) were dosed with the chemical at 500, 1000 or 2000 mg/kg bw via intraperitoneal injection. The chemical caused a statistically significant increase in the mean number of micronucleated polychromatic erythrocytes at all doses tested, in both sexes. On the basis of this finding, sodium formaldehyde sulfoxylate was determined to be genotoxic in vivo (REACH).

## **Carcinogenicity**

Based on the available information, no hazard classification for carcinogenicity is recommended. No reliable data are available for the formaldehyde sulfoxylate anion. Zinc salts were not considered to be carcinogenic (NICNAS).

## **Reproductive and Developmental Toxicity**

Based on the results of an OECD TG 414 study (prenatal developmental toxicity), the formaldehyde sulfoxylate anion is expected to cause developmental toxicity. Hazard classification for developmental toxicity is recommended.

Sodium formaldehyde sulfoxylate was assessed for its potential to cause reproductive toxicity according to OECD TG 422 (combined repeated dose toxicity study with the reproduction/developmental toxicity screening test). Wistar rats of both sexes (10 animals/group) were dosed with the chemical at 100, 300 or 1000 mg/kg bw/day via oral gavage. Males were treated for 30 days (two week prior to mating, during mating, and up to termination). Females were treated for 42-53 days (two weeks prior to mating, during mating, during post-coitum and during at least four days of lactation). Offspring were not treated. Parental toxicity was observed in the highest dose group with some animals exhibiting hunched posture and piloerection. Decreased body weight gain was also observed in the highest dose group. No reproduction, breeding and developmental toxicity was observed up to 1000 mg/kg bw/day. On the basis of these results, an NOAEL of 300 mg/kg bw/day was determined for parental toxicity and an NOAEL of 1000 mg/kg bw/day was determined for reproductive toxicity (REACH).

Sodium formaldehyde sulfoxylate was assessed for developmental toxicity in a study conducted according to OECD TG 414 (prenatal developmental toxicity study). Female Wistar rats (24 mated females/dose group) were orally administered the chemical at 100, 300 or 1000 mg/kg bw/day starting from day six until day 19 post coitum. No treatment-related deaths were recorded. No treatment-related clinical signs were observed during the dosing period. There was a decrease in body weight gain and food consumption in the high dose females. Skeletal examination of fetuses revealed dose-dependent impaired ossification. There was also an increase in the incidence of rib malformation in all groups. Visceral examination revealed anophthalmia in the low and high dose groups, and hydroureter and umbilical hernias at the highest dose. On the basis of these results, an NOAEL of 300 mg/kg bw/day was determined for maternal toxicity. No NOAEL could be identified for foetal toxicity given the effects seen at all dose levels (REACH).

Reproductive and developmental toxicity have been investigated in several studies using zinc sulfate. Studies in rats provide evidence that high doses of zinc adversely affect spermatogenesis in males and impair fertility in females. The very high concentrations of zinc compounds (equivalent to =1000 mg/kg bw/day zinc sulfate heptahydrate), required to produce these adverse effects do not satisfy the criteria for classification (NICNAS).

## **Risk Characterisation**

### **Critical Health Effects**

The critical health effects for risk characterisation include systemic long-term effects (genotoxicity and developmental toxicity), systemic acute effects (acute toxicity from oral exposure) and local effects (eye irritation).

### **Public Risk Characterisation**

At present, there is no evidence to suggest that the chemical is in use in cosmetic/domestic products in Australia. Although there are some reports indicating that the chemical is used in cosmetic/domestic products overseas as a reducing agent (CosIng), its use is not expected to be widespread (EWG; CIUCUS, 2011).

### **Occupational Risk Characterisation**

During product formulation, oral and ocular exposure may occur, particularly where manual or open processes are used. These could include transfer and blending activities, quality control analysis, and cleaning and maintaining 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 will vary depending on the method of application and work practices employed.

Given the critical systemic long-term, systemic acute and local health effects, the chemical could pose an unreasonable risk to workers unless adequate control measures to minimise exposure are implemented. The chemical 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 the appropriate controls.

The data available support an amendment to the hazard classification in the HSIS (Safe Work Australia) (refer to **Recommendation** section).

## NICNAS Recommendation

Assessment of the chemical is considered to be sufficient, provided that the recommended amendment to the classification is adopted, and labelling and all other requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory.

## Regulatory Control

### Public Health

Should information indicating that the chemical is used in cosmetic/domestic products in Australia become available in the future, further risk management may be required to protect public health.

### Work Health and Safety

The chemical is recommended for classification and labelling under the current approved criteria and adopted GHS as below. This assessment does not consider classification of physical and environmental hazards.

Hazard	Approved Criteria (HSIS) <sup>a</sup>	GHS Classification (HCIS) <sup>b</sup>
Acute Toxicity	Harmful if swallowed (Xn; R22)	Harmful if swallowed - Cat. 4 (H302)
Irritation / Corrosivity	Irritating to eyes (Xi; R36)	Causes serious eye irritation - Cat. 2A (H319)
Genotoxicity	Muta. Cat 3 - Possible risk of irreversible effects (Xn; R68)	Suspected of causing genetic defects - Cat. 2 (H341)
Reproductive and Developmental Toxicity	Repro. Cat 3 - Possible risk of harm to the unborn child (Xn; R63)	Suspected of damaging the unborn child - Cat. 2 (H361d)

<sup>a</sup> Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].

<sup>b</sup> 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 industry

### Control measures

Control measures to minimise the risk from oral and ocular 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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