Australian Government
Department of Health, Disability and Ageing
Australian Industrial Chemicals Introduction Scheme

Phosphonic acid, *P*-(1,1-dimethylethyl)-, calcium salt (1:1)

Assessment statement (CA09969)

1 October 2025

Table of contents

AICIS assessment (CA09969)

Chemical in this assessment

Name	CAS registry number
Phosphonic acid, *P*-(1,1-dimethylethyl)-, calcium salt (1:1)	81607-35-4

Reason for the assessment

An application for an assessment certificate under section 31 of the *Industrial Chemicals Act 2019* (the Act).

Certificate application type

AICIS received the application in a Health Focus type.

Defined scope of assessment

The chemical has been assessed:

- as imported into Australia at up to 10 tonnes/year as a constituent of ready-to-use resin pellets at 0.15% concentration
- for end use in the production of plastic and polymer products at a concentration of up to 0.15%, including for use in articles intended for food contact
- when used in articles intended for food contact, it is not included in articles in contact with infant formula or human milk

Summary of assessment

Summary of introduction, use and end use

The proposed introduction of the assessed chemical will be in a specified class of introduction, with an end use in an article with food contact (subsection 7(4)(b) of the *Industrial Chemicals (General) Rules 2019*).

The assessed chemical will not be manufactured in Australia. The assessed chemical at 0.15% concentration will be imported as a constituent of ready-to-use resin pellets for formulation of products in various package sizes.

The assessed chemical has functional use as a nucleating agent in the production of plastic and polymer products. The resin pellets will be melted and shaped into plastic articles by injection moulding, including articles intended for food contact for use by the public.

Human health

Summary of health hazards

The submitted toxicological data on the assessed chemical (see **Supporting information**) indicate that the chemical is:

- of low acute oral toxicity
- not irritating to the skin
- slightly irritating to the eyes but the data does not support classification
- not a skin sensitiser
- not genotoxic

A submitted repeat dose oral toxicity study on an analogue chemical (Phosphonic acid, *P*-methyl-, compd. with *N*-(aminoiminomethyl)urea (1:1); CAS registry number 84402-58-4) reported a no observed adverse effect level (NOAEL) of 1,000 mg/kg bw/day. However, there were uncertainties regarding the established NOAEL in the absence of a recovery period in the study as there were several mean organ weight changes in animals of all treatment groups (see **Supporting information**).

The assessed chemical is an organophosphorus compound. No acute or repeated dose inhalation toxicity data were provided for the assessed chemical. As the introduction concentration of the assessed chemical in Australia is at 0.15% in pellets, the lack of inhalation toxicity data will not impact this risk assessment.

Hazard classifications relevant for worker health and safety

Based on the data provided by the applicant, the assessed chemical does not 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 worker health and safety as adopted for industrial chemicals in Australia.

Summary of health risk

Public

Members of the public may come into contact with plastic and polymer products containing the assessed chemical at up to 0.15% concentration. The public could be exposed to the assessed chemical due to migration from food contact materials into food. Given the proposed low end use concentration, the assessed chemical is unlikely to cause systemic health effects from repeated exposure to articles containing it. In addition, a migration study on the assessed chemical showed that levels of it migrating into food simulants under all conditions tested were near or below the limit of detection of 10 µg/kg (EFSA 2024).

The proposed concentration of use aligns with approved food contact use overseas. Refer to the **Supporting information** section of the statement for information on the international regulatory status of the chemical. Overall, based on available data the chemical is unlikely to pose a risk to the public and no specific risk management measures are required.

As the assessed chemical will be used in materials with direct food contact, this assessment statement will be forwarded to Food Standards Australia New Zealand (FSANZ) for their consideration.

Workers

The assessed chemical will be introduced and used at a low concentration in end use products/articles (0.15%). Production processes of articles will be automated and carried out in purpose-built facilities fitted with vacuum extraction equipment, to minimise dust/particle exposure (see **Supporting information** section). When introduced and used in the proposed manner, it is unlikely that workers will be exposed to the assessed chemical during article manufacturing as the chemical will be encapsulated within the pellets and in moulded articles.

This assessment does not identify any risks to workers that would require specific risk management measures. In the absence of inhalation data, control measures to minimise exposure are recommended (see **Means for managing risk**).

Environment

Summary of environmental hazard characteristics

According to the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* (DCCEEW 2022) and based on the available data the assessed chemical is:

- Persistent (P)
- Not Bioaccumulative (not B)
- Not Toxic (not T)

Environmental hazard classification

Based on the ecotoxicological data available for the assessed chemical, it is not expected to be harmful to aquatic life. Therefore, the assessed chemical does not satisfy the criteria for classification under the GHS for acute and chronic aquatic toxicities (UNECE 2017).

Summary of environmental risk

No significant release of the assessed chemical is expected to occur as a result of its use in the production of plastic and polymer products. The assessed chemical is expected to share the fate of the plastic articles it is incorporated into and be disposed of to landfill or collected for recycling at the end of its useful life.

Although the assessed chemical is persistent according to the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* (DCCEEW 2022), it does not meet all three PBT criteria. It is hence unlikely to have unpredictable long-term effects. The available ecotoxicity data demonstrate that the assessed chemical is not expected to be harmful to aquatic organisms. Based on its low hazards and the assessed use pattern, the environmental risk from the introduction of the assessed chemical can be managed.

Means for managing risk

Workers

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.

The following control measures could be implemented to manage the risk arising from exposure to the assessed chemical during production of plastic and polymer products:

- Use of safe work practices to
  - Avoid inhalation of dusts or aerosols

- Use of personal protective equipment (PPE)
  - Respiratory protection where local ventilation may be inadequate

Conclusions

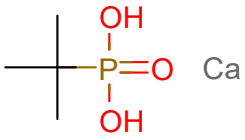
The Executive Director is satisfied that the risks to human health or the environment associated with the introduction and use of the industrial chemical can be managed.

Note:

1. Obligations to report additional information about hazards under s 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

CAS number	81607-35-4
CAS name	Phosphonic acid, *P*-(1,1-dimethylethyl)-, calcium salt (1:1)
Molecular formula*	$C_4H_{11}O_3P.Ca$
Molecular weight (g/mol)*	178.18
SMILES (canonical)*	[Ca].O=P(O)(O)C(C)(C)C
Representative structure*	

Additional chemical identity information

The assessed chemical has a purity of greater than 97%.

* This chemical is a salt and has been represented according to CAS nomenclature/identity conventions.

Relevant physical and chemical properties

Physical form	White powder	
Melting point	> 370	°C
Boiling point	> 370	°C at 101.3 kPa
Density	1.2904	kg/m^3 at 20 °C
Water solubility	0.47	g/L at 20 °C
Particle Size	Inhalable fraction (< 100 µm): > 95 Respirable fraction (< 10 µm): > 90	% %
Ionisable in the environment	yes	
pK_a	2.79 and 8.88 (Freedman and Doak 1957)	
log K_{ow}	< -0.24 at pH 5	

International regulatory status

European Union

The applicant provided a safety assessment of the assessed chemical for use in food contact materials conducted by the European Food Safety Authority (EFSA)'s Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) (EFSA 2024). The CEP Panel concluded that the assessed chemical does not raise a safety concern for the consumer if it is used as a nucleating agent up to 0.15% w/w in polyolefin materials and articles intended for contact with all types of food for storage above 6 months at room temperature and below, including temperatures up to 100 °C for maximum 2 h and up to 130 °C for short durations. The Panel could not evaluate the safety of use of the assessed chemical to manufacture polyolefin materials and articles for contact with infant formula and human milk.

United States of America

The assessed chemical is listed on the U.S. Food and Drug Administration (FDA) *Inventory of Effective Food Contact Substance (FCS) Notifications* for use in contact with all types of foods under the prescribed conditions of use, including infant formula and human milk.

An extract from this FCS notification (FCN No. 2211) stipulates that use levels of the assessed chemical must not exceed:

- 0.15% (w/w) in polyolefins in contact with all food types under Conditions of Use A through H and J (microwave only, excluding susceptor applications).

Human exposure

Workers

At article production sites, the resin pellets containing the assessed chemical will be used in an injection-moulding process. The pellets containing the assessed chemical at 0.15% will be either transferred by vacuum or manually tipped into the feeding hopper on the injection-moulding machine. The pellets will then be fed into the barrel of the machine by gravity and heated. Once melted, the pellets will be injected into a mould to form the shape of the plastic article and then cooled, prior to ejection into a suitable receptacle.

Production processes including the delivery, mixing and dispensing processes used in casting operations are automated and are carried out in purpose-built facilities fitted with vacuum extraction equipment, to minimise release of fugitive particulate material (dust). According to the applicant, production workers will wear personal protective equipment including eye protection, chemical impermeable gloves, work clothing and, if local ventilation is inadequate, a particulate respirator with full head covering.

Occupational exposure to the assessed chemical is unlikely as it will be encapsulated within the pellets and in moulded articles. In this form, the chemical is not available for exposure, hence the risk to workers is expected to be negligible.

Public

The resin pellets containing the assessed chemical are intended for industrial use only and will not be sold or made available to the public. The assessed chemical will be incorporated into various plastic articles, including articles intended for food contact for use by the public at 0.15% concentration. Public exposure to the assessed chemical via dermal contact with these articles is not expected, except in the possible event of the chemical leaching from these articles.

Although food and beverages could be a source of public exposure, the assessed chemical at 0.15% will be encapsulated within the polymer matrix of the containers and negligible levels are expected to migrate into the food or beverage.

In the safety assessment conducted by EFSA, the CEP Panel noted that migration levels of the assessed chemical into food simulants under all conditions tested were near or below the limit of detection (10 µg/kg). Specific migration was tested using polyethylene samples in 10% ethanol, 3% acetic acid and 95% ethanol for 2 h at 100°C, followed by 238 h at 40°C. Results for all three simulants were near or below the limit of detection of 10 µg/kg. The EFSA CEP Panel concluded that the assessed chemical is not of safety concern for the consumer, if it is used as a nucleating agent up to 0.15% w/w in polyolefin materials and articles intended for contact with all types of food for storage above 6 months at room temperature and below, including temperatures up to 100 °C for maximum 2 h and up to 130 °C for short durations. The Panel could not evaluate the safety of use of the assessed chemical to manufacture polyolefin materials and articles for contact with infant formula and human milk (EFSA 2024).

Based on the end-use concentration of 0.15% specified in the defined scope of assessment, the assessed chemical is not expected to migrate into food at levels of concern.

Health hazard information

The applicant has provided study data on the assessed chemical for all required human health endpoints except repeat dose toxicity. The applicant provided analogue data for repeat dose oral toxicity.

Acute toxicity

Oral

In an acute oral toxicity study (OECD TG 423), female Sprague-Dawley rats were given a single dose of the assessed chemical by oral gavage (in corn oil) at 300 or 2,000 mg/kg bw (n = 6/dose). No mortality occurred during the study and there were no gross lesions observed upon necropsy following the observation period. There were no clinical signs attributed to the treatment.

In the 300 mg/kg bw group, body weight decreases were observed on day 3 and day 14 in one animal and on day 7 in another. In the 2,000 mg/kg bw group, body weight decreases were observed in 2 animals on day 7 after administration. However, the decreases were temporary and not considered to be related to treatment. The acute oral median lethal dose (LD50) value was determined to be > 2,000 mg/kg bw. Based on the results of this study, the assessed chemical is of low acute oral toxicity.

Corrosion/Irritation

Skin irritation

In an *in vivo* skin irritation study (OECD TG 404), 3 female New Zealand White (NZW) rabbits treated with 0.5 g of assessed chemical moistened with corn oil (semi-occlusive) for 4 hours developed no skin reactions up to 72 hours after exposure. Furthermore, no mortality occurred, and no symptoms of systemic toxicity were observed in the animals during the test period. Under the conditions of the study, the assessed chemical is not irritating to skin.

Eye irritation

In an *in vivo* eye irritation study (OECD TG 405), 0.1 g of the assessed chemical was instilled into the conjunctival sac of one eye of each of 3 female New Zealand White rabbits. Eye irritation was assessed at 1, 24, 48 and 72 hours after treatment. Redness (maximum score of 1) and swelling (maximum score of 2) of the conjunctiva were observed in all animals at 1 hour after application, but these effects were fully resolved by 24 hours. No other effects were observed at any time point during the study. Therefore, under the conditions of the study, the assessed chemical is slightly irritating to the eyes but does not meet the GHS criteria for classification.

Sensitisation

Skin sensitisation

In a modified local lymph node assay (LLNA) using non-radiolabelled 5-bromo-2-deoxyuridine (BrdU) in an Enzyme-Linked Immunosorbent Assay (ELISA) (BrdU-ELISA) (OECD TG 442B), the assessed chemical (in acetone:olive oil (4:1, v:v)) was applied to both ears of CBA/J mice (n = 5 females/dose) at 5% (w/v), 10% (w/v) and 25% (w/v) concentrations. The use of acetone:olive oil as the vehicle precluded testing of higher concentrations of the assessed chemical. No clinical signs of toxicity or changes in body weights or ear thickness were observed in response to the test substance. Stimulation indices (SI) of 1.3, 1.2 and 1.1 were obtained for the 5%, 10% and 25% concentrations, respectively. According to the test guideline, an SI > 1.6 is indicative of a sensitising response under this modified non-radioactive method. Therefore, under the conditions of the study, the assessed chemical is not a skin sensitiser.

Repeat dose toxicity

Oral

In a repeated dose oral toxicity study (OECD TG 408), an analogue chemical (Phosphonic acid, *P*-methyl-, compd. with *N*-(aminoiminomethyl)urea (1:1)) was administered to groups of Wistar rats (n = 10/sex/dose) by oral gavage at doses of 0 (vehicle control), 100, 300 and 1,000 mg/kg bw/day for 90 days. There were no mortalities observed throughout the course of the study. Food and water consumption were normal and there were no differences in body weight or body weight gain observed between treated animals and the respective control animals.

Statistically significant slight to moderate salivation and “moving the bedding” was observed in 4 low-dose males and all mid-dose and high-dose animals. It was noted that the increased salivation in high-dose females occurred from week 2 to week 11. The onset of these effects

closely followed administration of the chemical and so were considered to be a local reaction to the treatment by the study authors, rather than adverse systemic clinical effects. However, AICIS notes that salivation could be an effect related to the treatment, as the analogue chemical is an organophosphorous compound.

The only statistically significant haematological changes reported were a 71% decrease in eosinophil levels in mid-dose males and a 51% increase in monocyte levels in mid-dose females, relative to controls. There was a statistically significant 81% increase in T3 thyroid hormone in low-dose males and a 65% decrease in total bile acids in high-dose females but there were no related histopathological findings or dose response.

The following changes in organ weights were recorded, although these did not reach statistical significance. Mean relative thyroid/parathyroid weights were increased in low-dose and high-dose males (+11% and +16%, respectively). Other changes in male rats included an increase in absolute and relative pituitary weights at the low dose (+10% and +13%, respectively) and increases in absolute and relative prostate weights at the low and high doses. In low-dose males the absolute prostate weight increased by 11% and the relative weight increased by 14%. In high-dose males the absolute prostate weight increased by 13% and the relative weight increased by 11%. In females, absolute and relative thymus weights increased in the high-dose group by 17% and 16%, respectively. Absolute and relative thyroid/parathyroid weights in the mid-dose females increased by 16% and 15%, respectively. Mean ovary weight decreased in low-dose females by 10% (absolute) and 14% (relative). Mean relative pituitary weight decreased by 12% in low-dose females. In high-dose females, absolute and relative adrenal gland and uterus (with cervix) weights increased by 15% and 13%, respectively and by 24% and 24%, respectively. As all of these changes were isolated, not dose-dependent and did not correspond to histopathological changes, they were not considered to be treatment related.

At necropsy, 1 high-dose male had a cyst on the prostate gland and spotted harderian glands. 1 high-dose female had few black foci on the stomach and reddened axillary or mandibular lymph nodes were each reported in 1 high dose female. Uterus dilatation was reported in 1 control,1 mid-dose and 4 high-dose females. These findings were all considered to be incidental or representative of the normal physiology of the test species, rather than treatment related.

The no observed adverse effect level (NOAEL) in this study was reported to be 1,000 mg/kg bw/day. AICIS notes that there were several mean organ weight changes in animals of all treatment groups, and some above 10% of the relevant control groups. As there was no recovery period in the study, these changes could not be confirmed as reversible and non-adverse.

Genotoxicity

A study was performed to evaluate the potential of the assessed chemical to cause point mutations in a bacterial reverse mutation assay using *Salmonella typhimurium* strains TA98, TA100, TA1535 and TA1537 and *Escherichia coli* strain WP2*uvrA*, in both the presence and absence of metabolic activation (S9-mix) (OECD TG 471). No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any tested dose of the assessed chemical, either with or without metabolic activation. Under the conditions of this study, the assessed chemical did not cause point mutations.

The assessed chemical was tested for its clastogenic and aneugenic potential in an *in vitro* mammalian micronucleus test using human lymphocytes (OECD TG 487). The assessed chemical did not induce any statistically significant increases in the frequency of binucleate

cells with micronuclei in either the absence or presence of metabolic activation (S9-mix). Under the conditions of this study, the assessed chemical was non-clastogenic and non-aneugenic

Another *in vitro* study was performed to assess the potential of the assessed chemical to cause chromosomal aberrations in Chinese hamster lung (CHL) cells (OECD TG 473). No statistically significant increases in the incidence of chromosomal aberrations were observed with or without metabolic activation. Under the conditions of this study, the assessed chemical was non-clastogenic.

In an *in vivo* mammalian erythrocyte micronucleus test (OECD TG 474), ICR mice (n = 5 males/dose) were treated with the assessed chemical (in corn oil) by gavage at doses of 0, 500, 1,000 and 2,000 mg/kg bw/day, once daily for 2 days. No abnormal clinical signs or deaths were reported in any dose group. The incidence of micronuclei in bone marrow polychromatic erythrocytes did not increase in any of the treated groups compared to the control group. Under the conditions of this study, the assessed chemical was not clastogenic.

Neurotoxicity

No neurotoxicity studies were provided by the applicant.

The EFSA safety assessment of the assessed chemical states that organophosphorus compounds require special attention due to their potential to trigger neurotoxicity. It was noted that exposure to the assessed chemical resulting from migration was below the threshold of toxicological concern for organophosphates (18 µg/person/day). Therefore, the EFSA CEP panel concluded that use of the assessed chemical does not give rise to a safety concern related to neurotoxicity for the general population. However, this could not be applied to infants below 16 weeks of age due to their specific sensitivity and to the absence of dedicated data to rule out neurotoxicity. Thus, the safety of the use of the assessed chemical to manufacture polyolefin materials and articles for contact with infant formula and human milk could not be evaluated (EFSA 2024).

Environmental exposure

Significant release of the assessed chemical to the environment is not expected during transport or storage. Release of the assessed chemical to the environment due to accidental spills is expected to be collected and recycled or disposed of in accordance with relevant Local, State, Territory and Federal regulations.

The assessed chemical will be used as a nucleating agent in the production of plastic and polymer products by injection moulding. Significant release of the assessed chemical to the environment is not expected during use as the majority of the assessed chemical will be incorporated in the moulded articles. Washes from equipment cleanouts are expected to be collected, treated, and disposed of by appropriate accredited waste management facilities in accordance with relevant Local, State, Territory and Federal regulations.

The assessed chemical will share the fate of the moulded articles in which they have been incorporated. The incorporated articles may enter recycling streams but will ultimately be disposed of to landfill at the end of the articles' useful life.

Environmental fate

Partitioning

The assessed chemical has a very low log K_{ow} value (log K_{ow} < -0.24). Therefore, it is expected to have high mobility in soil and sediment compartments.

The assessed chemical is readily soluble in water (water solubility = 0.47 g/L at 20°C). If the assessed chemical is released to surface water, it is expected to mainly remain in the water compartment based on its ready solubility in water and very low log K_{ow}.

The assessed chemical is not expected to be volatile under environmentally relevant conditions.

Degradation

Based on its measured biodegradability in water, the assessed chemical is categorised as persistent.

The result of a biodegradation study supplied for the assessed chemical (OECD 301F) showed no degradation over 28 days. Therefore, the assessed chemical is not readily biodegradable.

Bioaccumulation

Based on its very low log K_{ow} value, the assessed chemical is categorised as not bioaccumulative.

No bioaccumulation information was provided for the assessed chemical. The experimental partition coefficient of the assessed chemical is log K_{ow} < -0.24, below the domestic bioaccumulation threshold of log K_{ow} = 4.2 (EPHC 2009).

Predicted environmental concentration (PEC)

A predicted environmental concentration (PEC) has not been calculated as the assessed chemical is not expected to be released into the aquatic environment under the assessed use pattern.

Environmental effects

Effects on aquatic Life

Acute toxicity

The following median lethal concentration (LC50) and median effective concentration (EC50) values for model organisms were supplied for the assessed chemical:

Taxon	Endpoint	Method
Fish	96 h LC50 > 100 mg/L	*Gobiocypris rarus* (Rare minnow) Mortality OECD TG 203 Static conditions Nominal concentration
Invertebrate	48 h EC50 > 100 mg/L	*Daphnia magna* (Water flea) Immobility OECD TG 202 Static conditions Nominal concentration
Algae	72 h ErC50 > 152.15 mg/L	*Pseudokirchneriella subcapitata* (Green algae) Growth inhibition OECD TG 201 Static conditions Measured concentration

Chronic toxicity

The following measured 10th percentile effective concentration (EC10) value for a model organism was supplied for the assessed chemical.

Taxon	Endpoint	Method
Freshwater algae	72 h ErC10 = 76.98 mg/L	*Pseudokirchneriella subcapitata* (Green algae) Growth inhibition OECD TG 201 Static conditions Measured concentration

Predicted no-effect concentration (PNEC)

A predicted no-effect concentration (PNEC) has not been calculated as the assessed chemical is not expected to be harmful to aquatic organisms.

Categorisation of environmental hazard

The categorisation of the environmental hazards of the assessed chemical according to the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals* (DCCEEW 2022) is presented below:

Persistence

Persistent (P). Based on a measured degradation study, the assessed chemical is categorised as Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on the low measured log K_{ow} value, assessed chemical is categorised as Not Bioaccumulative.

Toxicity

Not Toxic (Not T). Based on available ecotoxicity values above 1 mg/L, the assessed chemical is categorised as Not Toxic.

Environmental risk characterisation

Although the assessed chemical is persistent, it does not meet all three PBT criteria. It is hence unlikely to have unpredictable long-term effects (EPHC 2009). The available ecotoxicity data demonstrate that the assessed chemical is not expected to be harmful to aquatic organisms.

A Risk Quotient (PEC/PNEC) for the aquatic compartment could not be calculated. However, the assessed chemical is not expected to be harmful to aquatic life, and release of the assessed chemical to the aquatic environment will be negligible based on its assessed use pattern. Therefore, based on the low environmental hazard characteristics and negligible exposure, the environmental risk from the introduction of the assessed chemical can be managed.

References

DCCEEW (Department of Climate Change, Energy, the Environment and Water) (2022) *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals*, DCCEEW, accessed 9 July 2025.

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