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

Phosphorous acid, triphenyl ester, polymer with 1,4-cyclohexanedimethanol and .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C_{10-16}-alkyl esters

Assessment statement (CA09853)

27 March 2026

Table of contents

AICIS assessment (CA09853)

Chemical in this assessment

Name	CAS registry number
Phosphorous acid, triphenyl ester, polymer with 1,4-cyclohexanedimethanol and .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C_{10-16}-alkyl esters	1821217-71-3

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 Very Low to Low Risk type.

Defined scope of assessment

The polymer has been assessed:

- as imported into Australia at up to 1 tonne/year
- as imported into Australia neat as a liquid, or at up to 8% in masterbatch pellets
- 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 use
- when used in articles intended for food contact use:
    - the polymer is not included in articles in contact with infant formula or human milk
    - the polymer has a low molecular weight fraction (less than 1,000 g/mol) of up to 13% concentration

Summary of assessment

Summary of introduction, use and end use

The proposed introduction of the assessed polymer 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 polymer will not be manufactured in Australia. It will be imported as a neat liquid for use as an antioxidant additive in various plastic products, including articles intended for food contact for use by the public. It will also be imported at up to 8% in masterbatch pellets.

The assessed polymer, as introduced neat, will be added directly to the intermediate plastic polymer as it passes through the extruder and mixed together during passage through the extruder. The finished plastic polymer, as it exits the extruder, will be shaped into pellets

containing the assessed polymer at up to 0.15% concentration. These pellets will then be re-melted to create final plastic articles for use by the general public.

When introduced as masterbatch pellets containing the assessed polymer at up to 8%, these will be mixed with other pellets during production of the final plastic articles. The concentration of the assessed polymer in the final plastic articles will be up to 0.15% concentration.

Human health

Summary of health hazards

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

- Sensitising to skin
- Not genotoxic
- Not neurotoxic

In a local lymph node assay (LLNA) study with the assessed polymer, the concentration producing a 3-fold increase in lymphocyte proliferation (EC3) was calculated to be 23.12%.

No data were submitted by the applicant on acute toxicity, skin or eye irritation.

The submitted toxicological data on a low molecular weight 50:50 blend of the phosphite/phosphate forms of the assessed polymer (see **Supporting information**) indicate that the polymer:

- is not likely to cause systemic health effects following repeated oral exposure for 90 days at 500 mg/kg bw/day (equivalent to 250 mg/kg bw/day of each form of the assessed polymer in the test substance).

The accumulation potential of the low molecular weight phosphite and phosphate fractions of the assessed polymer in humans does not raise a toxicological concern (EFSA CEP Panel *et al,* 2024).

Hazard classifications relevant for worker health and safety

Based on the data provided by the applicant, the assessed polymer satisfies 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.

Health hazards	Hazard category	Hazard statement
Skin sensitisation	Skin Sens. 1B	H317: May cause an allergic skin reaction

Summary of health risk

Public

Members of the public may come into contact with articles made from plastic and polymer products containing the assessed polymer at up to 0.15% concentration. While information on the acute toxicity, skin irritation or eye irritation potential of the assessed polymer has not been

submitted, effects to the public are not expected at the low concentration of end use (up to 0.15%).

The public could be exposed to the assessed polymer due to migration from food contact materials into food. No significant systemic toxicity effects were observed in available toxicological studies. The assessed polymer is used at a low concentration which minimises the extent of exposure. In addition, as any migration from food contact materials is expected to involve only low molecular weight species less than 1,000 g/mol of the assessed polymer, limiting these species to less than 13% concentration is expected to minimise migration to food.

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 polymer.

Overall based on available data the polymer is unlikely to pose a risk to the public and no specific risk management measures are required.

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

Workers

Potential exposure of workers to the assessed polymer at up to 100% concentration as a liquid may occur during reformulation and equipment maintenance (see **Supporting information** section). The principal routes of exposure will be dermal and ocular.

Occupational exposure to the assessed polymer at up to 8% concentration in masterbatch pellets or at up to 0.15% concentration in end use pellets and finished plastic articles is expected to be very low. In this form the assessed polymer will be incorporated within the polymeric matrix of the masterbatch pellets, end use polymer pellets and finished plastic articles.

Given the risk of skin sensitisation, control measures to minimise dermal exposure to the assessed polymer as introduced in liquid form are required to manage the risks to workers. As no data was provided on eye irritation, eye protection may be required (see **Means for managing risk** section).

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 polymer is:

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

Environmental hazard classification

Based on the ecotoxicological information available for the assessed polymer, it is not expected to be harmful to aquatic life. Therefore, the assessed polymer does not satisfy the criteria for classification under the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) for acute and chronic aquatic toxicities (UNECE, 2017).

Summary of environmental risk

The assessed polymer will be imported into Australia for end use as an antioxidant in the production of plastic and polymer products. The assessed introduction does not meet any of the *Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals*. It is hence unlikely to have unpredictable long-term effects. The assessed polymer is not expected to be harmful to aquatic life or earthworms. In addition, significant release of the assessed polymer to the aquatic environment is not expected under the assessed use as the assessed polymer will share the fate of the plastics it is incorporated into and will be disposed to landfill at the end of its useful life. On the basis of the low hazard and the limited environmental exposure from the assessed use, the assessed polymer is not expected to pose significant risk to the aquatic environment. As such, the risk from the introduction of the assessed polymer can be managed.

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 (see **Hazard classifications relevant for worker health and safety**).

Information relating to safe introduction and use

The information in this statement, including the recommended hazard classification, 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 neat assessed polymer during the production of plastic pellets:

- Use of engineering controls such as
  - Enclosed and automated systems where possible
- Use of safe work practices to
  - Avoid contact with skin and eyes
- Use of personal protective equipment (PPE)
  - Face shield
  - Impervious gloves
  - Protective clothing

- The storage of the assessed polymer should be in accordance with the Safe Work Australia *Code of Practice for Managing Risks of Hazardous Chemicals in the Workplace* (SWA 2023) or relevant State or Territory Code of Practice.

- As the assessed polymer is a skin sensitiser, control measures may need to be supplemented with health monitoring for any worker who is at significant risk of exposure to the polymer, if valid techniques are available to monitor the effect on the worker's health.

- A copy of the Safety Data Sheet (SDS) should be easily accessible to workers.

Conclusions

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

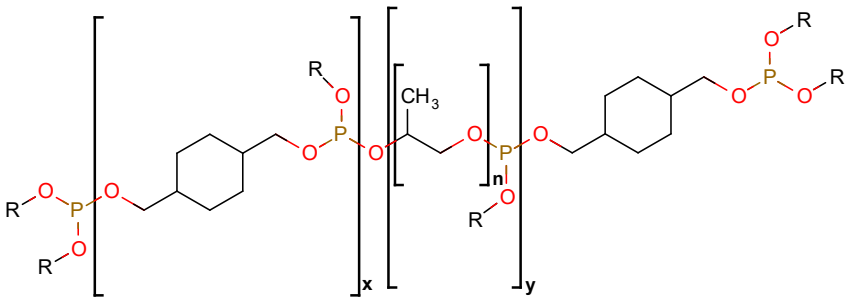
Note:

1. Obligations to report additional information about hazards under s 100 of the *Industrial Chemicals Act 2019* apply.
2. A person introducing this chemical should be aware of their obligations under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Supporting information

Chemical identity

CAS number	1821217-71-3
CAS name	Phosphorous acid, triphenyl ester, polymer with 1,4-cyclohexanedimethanol and .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C_{10-16}-alkyl esters
Molecular formula	Unspecified
Molecular weight (g/mol)	> 1,000
Percentage of low molecular weight species w/w (less than 1,000 g/mol)	≤ 13
Representative structure	



R = C_{10-16}-alkyl esters

Relevant physical and chemical properties

Physical form	Clear, oil-like liquid
Melting point	- 10 °C
Boiling point	Thermally degrades prior to reaching boiling point.
Relative Density	0.961 at 25 °C
log K_{ow}	1.0
Water solubility /extractability	0.188 g/L at 20 °C
Ionisable in the environment	No

International regulatory status

European Union

The applicant provided a safety assessment of the assessed polymer for use in food contact materials, conducted by the European Food Safety Authority (EFSA) Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) (EFSA CEP Panel *et al*, 2024). The contact with infant formulae and human milk was not specified as an intended application of the substance and therefore it was not considered in the assessment.

The Panel concluded that the assessed polymer does not raise a safety concern for the consumer if:

- its low molecular weight fraction (LMWF: the portion of the polymer below 1,000 g/mol) is not higher than 13% w/w concentration and;
- it is used at up to 0.15% concentration in polyolefin materials and articles intended for contact with all food types (except for infant formula and human milk):
    - for long-term storage at room temperature and below
    - including hot-fill and/or heating up to 100 °C for up to 2 h; and
- the migration of the total of phosphite and phosphate species does not exceed 5 mg/kg food.

United States of America

The assessed polymer 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, except for infant formula and human milk.

An extract from this FCS notification (FCN No. 2292) stipulates that use levels of the assessed polymer must not exceed:

- 0.2% concentration in linear low-density polyethylene (LLDPE) in contact with all types of food under Conditions of Use A through H of the FCS notification
- 0.15% concentration in high-density polyethylene (HDPE) in contact with all types of food under Conditions of Use B through H of the FCS notification.

Human exposure

Workers

When imported as a neat liquid, the assessed polymer will be used as an antioxidant additive in a standard gas phase reactor process used for plastic polymer product manufacture. The assessed polymer will be transported to the site via tank truck and transferred from the tank to an on-site storage container. The assessed polymer will be directly transferred to the extruder from the container as the intermediate plastic polymer passes through the extruder, mixing these components in the process. The finished plastic polymer, as it exits the extruder, will be shaped into pellets containing the assessed polymer at up to 0.15% concentration.

Transfer steps involving the assessed polymer at 100% concentration are anticipated to occur via closed, automated systems of pumps and hoses. Dermal exposure to the assessed polymer at up to 100% concentration may occur during transfer activities and equipment maintenance and ocular exposure to the assessed polymer at this concentration may occur from accidental splashing during these procedures. Inhalation exposure to the assessed

polymer is not expected, unless aerosols are generated. The applicant anticipates that exposure of workers to the assessed polymer at up to 100% concentration will be minimised, provided the storage container is handled in accordance with workplace procedures, the storage container valves are properly closed off prior to hose removal and appropriate personal protective equipment (PPE) is worn by workers. The SDS of the assessed polymer at neat concentration recommends the use of PPE including face shields, suitable protective gloves and chemical-resistant clothing.

It is expected the pellets containing the assessed polymer at up to 0.15% concentration and the imported masterbatch pellets containing the assessed polymer at up to 8% concentration will be distributed to industrial customers to create final plastic articles containing the assessed polymer at up to 0.15% concentration. This process is expected to involve melting the plastic pellets and re-forming them to the intended shapes of the plastic articles for public use. Occupational exposure to the assessed polymer, as incorporated in masterbatch pellets at up to 8% concentration and in finished plastic pellets and moulded plastic articles at up to 0.15% concentration is expected to be very low. In this form, the polymer is incorporated in the polymer matrix.

Public

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

Where the articles have food contact uses, food and beverages could be a source of public exposure to the assessed polymer if it migrates into the food or beverages. The US FDA estimated the Cumulative Estimated Daily Intake (CEDI) of the assessed polymer to be 1.8 µg/kg bw/day (US FDA, 2024).

In the safety assessment conducted by EFSA (EFSA CEP Panel *et al*, 2024) the Panel noted that levels of the assessed polymer migrating into fatty foods may exceed 5 mg/kg food, provided some or all of the parameters that influence migration are worst-case, including a high LLDPE thickness of 508 µm and a food contact exposure period of 10 days at 60°C (as per Regulation (EU) 10/2011). However, the Panel did note that the modelled worst-case migration of the LMWF from a 250-µm-thick LLDPE sample using the testing conditions required in Regulation (EU) 10/2011 was 2.61 mg/kg food. The Panel also noted that milder conditions of use (e.g. a lower use level, smaller LMWF, shorter contact time and lower temperature) would decrease the migration levels of the assessed polymer. Furthermore, the migration of the assessed polymer into aqueous food stuffs was noted by the Panel to be limited by the low solubility of the polymer in aqueous media. The Panel concluded “that the substance does not raise safety concern if its migration does not exceed 5 mg/kg."

This migration was only exceeded in a modelled worst-case scenario [maximum intended use level, high polymer thickness (508 µm), a highly lipophilic simulant (olive oil) and a polyolefin with the highest diffusivity (LLDPE)], resulting in a migration of 5.3 mg/kg. Under normal conditions of use, migration is not expected to exceed the migration limit of 5 mg/kg. Limiting the low molecular weight species to 13% concentration or below should ensure that the migration limit is not exceeded, as it is only species < 1,000 g/mol that are expected to migrate.

It is noted that a migration limit of 5 mg/kg food is included in the safety assessment carried out by the European Food Safety Authority (EFSA) Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) (EFSA CEP Panel *et al*, 2024). This is based on several

considerations, including the tiered data requirements in the EU related to different migration levels.

Health hazard information

Sensitisation

Skin sensitisation

The skin sensitisation potential of the assessed polymer was tested using the local lymph node assay (LLNA) in mice (OECD TG 429). Three groups of female CBA/J mice (n = 5/dose) received topical applications of 25 µL of the assessed polymer at concentrations of 25% and 50% in methyl ethyl ketone or 100%, to the dorsal surface of each ear for 3 consecutive days (days 0, 1 and 2). A control group of 5 female mice was treated with the vehicle (methyl ethyl ketone) only. An additional group of 5 female mice was treated with the positive control (25% α-Hexylcinnamaldehyde in vehicle) only. At the end of the study (day 5), the draining auricular lymph nodes of all mice from all treatment, vehicle and positive control groups were excised. Single cell suspensions were prepared from each mouse and measured for radioactivity to calculate cellular proliferation responses.

No signs of systemic toxicity were observed in all treatment, vehicle and positive control groups. No signs of local irritation were observed in all treatment and vehicle groups. All mice in the positive control group displayed very slight erythema during study days 1 to 4, which resolved by day 5. No significant increase in ear thickness was noted in the treated animals. The stimulation indices (SI) at 25%, 50% and 100% concentration were 3.22, 5.20 and 8.53, respectively, indicating the assessed polymer to be a skin sensitiser. As all tested doses of the assessed polymer showed SI > 3, the estimated lowest concentration of a test substance needed to produce an SI of three (EC3) was calculated by log-linear interpolation of the two lowest doses of the assessed polymer used in the study. The EC3 value for the assessed polymer was calculated to be 23.12%, warranting GHS classification Category 1B for the assessed polymer for skin sensitisation (UNECE 2017).

Repeat dose toxicity

Oral (28-day study- phosphite)

In a repeated dose oral toxicity range finding study (based on OECD TG 407), a low molecular weight phosphite form of the assessed polymer (containing 40.6% < 1,000 Da) was administered to Wistar rats (n = 10/sex/group) by oral gavage at 0, 100, 330 and 1,000 mg/kg bw/day in corn oil for 28 days. Additional control and high dose groups were assigned as a 14-day recovery cohort (n = 10/sex/dose). The study protocol did not include haematology or clinical chemistry, and microscopic examination of organs was limited to the liver and spleen.

There were no unscheduled deaths. No treatment-related changes in the behavioural parameters, sensory reactivity, or body weight gain were observed.

A statistically significant decrease in mean ambulatory and mean total motor activity (25% and 23%, respectively) was observed in female rats treated at 1,000 mg/kg bw/day at 21 - 30 minutes post dosing (during functional observational battery in week 4), compared to the control group. Non statistically significant decreases in these parameters were also seen in the low and mid dose females, suggesting that the effects may be treatment related.

Statistically significant increases in the absolute and relative combined weights of the thyroid and parathyroid glands were seen in high dose males and in low, mid and high dose females. This effect was resolved in the high dose male recovery group, but continued to be statistically significant, to a reduced extent, in the female high dose recovery group. No correlating macroscopic changes were seen.

Decreases in absolute and relative heart weight in high and mid dose males (some of which were statistically significant), were reversed in high dose recovery males.

The female high dose group displayed a statistically significant 15% increase in relative liver weight and a noticeable increase of 14% in absolute liver weight, compared to controls. These effects were reversed in the high dose female recovery group.

Oral (28-day study - phosphate)

In a repeated dose oral toxicity range finding study (based on OECD TG 407), a low molecular weight phosphate form of the assessed polymer (containing 43.9% < 1,000 Da) in corn oil as vehicle was administered to Wistar rats (n = 10/sex/dose) via oral gavage for 28 days at dose levels of 0, 100, 330 and 1,000 mg/kg bw/day. A high dose recovery group was also maintained (14 days). The study protocol did not include haematology or clinical chemistry, and microscopic examination of organs was limited to the liver and spleen.

No unscheduled mortalities were recorded. No treatment-related changes in the behavioural parameters, functional performance parameters, sensory reactivity or body weight gain were observed.

Statistically significant increases in absolute and relative combined thyroid and parathyroid weights were observed in high dose males and females, and in the absolute weight for mid-dose males. These effects resolved in the recovery groups. No relevant macroscopic changes were observed at autopsy.

Dose related yellowish black deposits were observed in sinusoidal/Kupffer cells in the liver, primarily in females (in high dose recovery males and in low, mid, high and high dose recovery females). Similar deposits were seen in red pulp/macrophages in spleen (mid, high and high dose recovery males and in low, mid, high and high dose recovery females). Presence of the deposit in macrophages was indication of a clearance mechanism; however, the deposits were still present at 14 days of recovery period observation. These deposits were negative in haemosiderin, bilirubin and lipofuscin special staining methods. Scanning electron microscopy and energy dispersive X-ray analysis suggested the presence of iron (Fe) and phosphorous (P). No abnormalities were seen in the macroscopic examination of liver or spleen. As the severity of the deposits was minimal to mild, this effect was not considered as adverse at concentrations up to 1,000 mg/kg bw/day.

Oral (90-day study)

In a repeated dose oral toxicity study (OECD TG 408) the test substance (50:50 blend of phosphite/phosphate versions of a low molecular weight form of the polymer) in corn oil as vehicle was administered to Wistar rats (n = 25/sex/dose) via oral gavage for 90 days at dose levels of 0, 15, 50, 150 and 500 mg/kg bw/day (designated as the vehicle control, low, mid-low, mid and high doses, respectively). This equates to concentrations of 0, 7.5, 25, 75 and 250 mg/kg bw/day of each form of the assessed polymer. Recovery groups (n = 30/sex/dose) were also included in the study and observed for an additional 28, 56 and 90 days.

No treatment-related changes in the behavioural parameters, functional performance parameters, sensory reactivity, body weight gain, ophthalmology, vaginal smear examination or urinalysis were observed. Neurotoxicity was not seen in the pathological investigations made for this endpoint. Statistically significant but inconsistent and irregular food consumption patterns were observed in all dose groups (in both sexes) and these were considered as spontaneous. Various statistically significant changes in haematology and urinalysis parameters were not considered test item related as they were inconsistent, not dose related, or were within historical values.

One male rat died on day 90 in the mid-low dose recovery group. Based on macroscopic and microscopic examination, the study authors stated the mortality could be due to kidney dysfunction and considered it incidental. No other unscheduled mortalities were reported.

High dose (both main and recovery group) males and females showed dose related salivation during 54 to 79 days of treatment. Mid and high dose recovery females showed statistically significant but not dose related foot splay values. These effects were not considered as adverse in the study.

Statistically significant increases in low density lipoprotein (LDL) were found during week 7 of the dosing period in some dose groups of the recovery animals (mid-low and mid dose males and mid-low and high dose females). However similar increases did not occur in the equivalent main groups. An LDL level increase was also observed in high dose main group females at terminal autopsy and was considered treatment related. As no similar effects were observed in high density lipoprotein, cholesterol, or triglyceride, this effect was considered as mild and not adverse. Other statistically significant changes were identified in various clinical chemistry parameters but were not considered treatment related as they were inconsistent, not dose related or within historical values.

Levels of TSH, T3 and T4 were measured in terminal and recovery sacrifice animals. Statistically significant reductions in T4 were seen in low, mid-low and mid dose treatment females, but were not seen in the high dose or in any recovery animals. Hence, these effects were not considered to be treatment related.

A small number of isolated statistically significant changes in organ weights of different recovery groups at different times and doses were noted (spleen, uterus with cervix and testes) but were not dose related and were not considered treatment related. The increase in combined thyroid/parathyroid weight seen in the 28-day studies did not occur in this study.

Treatment related yellowish black pigment deposits were observed in the liver (both sexes at all dose levels), lungs (all doses in males and mid-low, mid and high dose females), mesenteric lymph nodes (mid-low, mid and high doses in both sexes) and spleen (all doses in males and mid-low, mid and high doses in females), and were also observed in recovery animals. However no adverse related effects in the affected organs were observed. Some of the pigment deposits were also observed in macrophages of these organs and these could be due to possible clearance of these deposits. The identity of the pigment deposits in the liver was investigated and was found to contain iron phosphate; this was not considered to have an adverse effect. Examination of the lungs also revealed chronic alveolar inflammation and increased macrophages, and the deposition in this organ was likely caused by aspirational pneumonia related to dosing. Deposits in the mesenteric lymph nodes were considered to be mostly hemosiderin. It was unclear whether the deposits in the spleen were the same as in the liver and lungs, or if they consisted of hemosiderin and/or artefactual pigments.

This study was also summarised in a safety assessment of the assessed polymer for use in food contact materials. This assessment, provided by the applicant, was conducted by the

European Food Safety Authority (EFSA) Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) (EFSA CEP Panel *et al*, 2024). In their summary, the EFSA CEP Panel concluded that:

“The pigment was identified as mainly iron phosphate. It was considered not to be of biological organic origin and did not represent natural pigments (e.g. lipofuscin) that are indicative of toxicity. The pigmentation did not completely clear within the recovery periods and was observed mainly in macrophages and Kupffer cells, suggesting a continuous clearance mechanism from the circulation. Due to the chemical properties of phosphoproteins and their binding affinity to iron, the long-lasting appearance of pigment (iron phosphate) can be expected. In the absence of accompanying haematology and clinical chemistry changes (i.e. indicators of liver function), this deposition can be considered as not adverse at the tested doses."

The safety assessment also discussed the accumulation potential of the assessed polymer in humans. In their discussion, the EFSA CEP Panel stated:

“Considering their intra-cytoplasmic distribution, their size (< 1 µm) and their round shape, the pigments were considered to be stored in lysosomes. They were also observed in macrophages, pointing to a clearance mechanism from the circulation. Finally, the pigment-laden macrophages present in liver, spleen and mesenteric lymph nodes were not accompanied by any histopathological changes in the corresponding tissues.”

The Panel concluded that the accumulation potential of low molecular weight fraction (LMWF) phosphite and phosphate in humans does not raise a toxicological concern."

Overall, the NOAEL for this study was determined to be 500 mg/kg bw/day (equivalent to 250 mg/kg bw/day of each form of the assessed polymer in the test substance).

Genotoxicity

No genotoxicity studies were provided by the applicant.

Three genotoxicity studies carried out to OECD Guidelines and following GLP were summarised in a safety assessment of the assessed polymer for use in food contact materials. This assessment, provided by the applicant, was conducted by the European Food Safety Authority (EFSA) Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) (EFSA CEP Panel *et al*, 2024). The EFSA CEP Panel notes that the assessed polymer enriched in its phosphite low molecular weight fraction (LMWF) and the assessed polymer enriched in its phosphate LMWF were independently tested in a battery of genotoxicity studies.

Both substances were tested with four strains of *Salmonella typhimurium* (TA98, TA100, TA1535 and TA 1537) and *Escherichia coli* WP2 *uvrA*/pKM101 in the bacterial reverse mutation assay (Ames Test, OECD TG 471) and concluded not to be mutagenic, with or without metabolic activation.

Both substances were tested in the *in vitro* mammalian cell micronucleus test (OECD TG 487) using human peripheral lymphocytes. They were found not to be clastogenic during short- and long-term treatment, with or without metabolic activation.

In the *in vitro* mammalian cell gene mutation test using the thymidine kinase gene (OECD TG 490) and the L5178Y cell line, a statistically significant increase in mutation frequency was observed at the second highest dose of the phosphite low molecular weight fraction test

substance, in the presence of metabolic activation. The highest dose of this test substance displayed cytotoxicity, both in the presence and absence of metabolic activation. The significant increase in mutation frequency was noted by the EFSA Panel to be in the range of negative historical controls. For the phosphate low molecular weight fraction test substance, no cytotoxicity was noted and the mutation frequency at all dose levels was comparable to the vehicle control, in the presence and absence of metabolic activation. The EFSA Panel concluded that both test substances did not induce gene mutation in mammalian cells under the test conditions applied.

Overall, the assessed polymer is not considered to be genotoxic.

Neurotoxicity

No neurotoxicity studies were provided by the applicant.

The EFSA safety assessment of the assessed polymer summarised two neurotoxicity studies conducted in hens (OECD TG 418). The test substance for one study was the assessed polymer enriched in its phosphite LMWF; the test substance for the other study was the assessed polymer enriched in the phosphate LMWF. The EFSA Panel noted no reported gross pathological changes and histological alterations involving brain, spinal cord and peripheral nerves after treatment with each test substance. The EFSA Panel concluded that no neurotoxic potential could be demonstrated for the test substances under the conditions of these studies.

Environmental exposure

Any accidental release of the neat polymer or the plastic pellets during transport or storage is expected to be collected and disposed of by appropriate accredited waste management facilities in accordance with relevant local, State, Territory and Federal regulations.

The assessed polymer will be used as an antioxidant additive for plastics. The assessed polymer will be added during the extrusion stage of plastic polymer pellet production. Any excess plastic will be recycled into future batches. Washes from equipment cleanouts and empty packages 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 polymer is expected to be incorporated into the solid matrix and share the fate of the plastics it is incorporated in and will be disposed of to landfill at the end of its useful life.

Environmental fate

Partitioning

The assessed polymer is a non-ionic polymer which has high molecular weight (NAMW > 1,000 g/mol) and minimal low molecular weight (< 25% below 1,000 g/mol) material composition. Therefore, it is expected to have low mobility in soil and sediment (US EPA, 2013).

The assessed polymer is moderately water soluble (water solubility = 0.188 g/L). If the assessed polymer is released to surface waters, a proportion of the assessed polymer is expected to remain in water compartment and a proportion of it is expected to partition to sediment, based on its moderate water solubility and high molecular weight.

As the assessed polymer has a high molecular weight, its vapour pressure and volatility are expected to be negligible (US EPA, 2013).

Degradation

Based on its measured biodegradability in water, the assessed polymer is categorised as not persistent.

The result of a biodegradation study supplied for the assessed polymer was 68% degradation over 28 days based on BOD measurement, and 98% degradation over 28 days based on test substance measurement (OECD 301F). Therefore, the assessed polymer is categorised as not persistent.

Bioaccumulation

Based on its high molecular weight, the assessed polymer is considered not bioaccumulative.

No bioaccumulation information was provided for the assessed polymer. The assessed polymer has high molecular weight and minimal low molecular weight material composition, which is usually of low concern for bioaccumulation (US EPA, 2013). Therefore, the assessed polymer is considered not bioaccumulative.

Predicted environmental concentration (PEC)

The predicted environmental concentration was not calculated as significant release of the assessed polymer to the aquatic environment is not expected under the assessed use.

Environmental effects

Effects on aquatic life

Acute toxicity

The following measured median lethal loading (LL50) and median effective loading (EL50) values for model organisms were supplied for the assessed polymer:

Taxon	Endpoint	Method
Fish	96h LL50 > 100 mg/L	*Gobiocypris rarus* (Rare Minnow) OECD TG 203 Semi-static conditions Nominal loading rate
Invertebrate	48 h EL50 > 100 mg/L	*Daphnia magna* (Water flea) Immobility OECD TG 202 Semi-static conditions Nominal loading rate
Algae	72 h EL50 > 100 mg/L	*Pseudokirchneriella subcapitata* (Green Algae) Growth inhibition OECD TG 201 Static conditions Nominal loading rate

Chronic toxicity

The following 10th percentile effective loading (EL10) value for model organism was supplied for the assessed polymer:

Taxon	Endpoint	Method
Algae	72 h EL10 > 100 mg/L	*Pseudokirchneriella subcapitata* (Green Algae) Growth inhibition OECD TG 201 Static conditions Nominal loading rate

Effects on terrestrial life

The following measured no-observed-effect concentration (NOEC) was supplied for the assessed polymer:

Taxon	Endpoint	Method
Earthworms	14 d NOEC ≥ 1,000 mg/kg soil dry weight*	*Eisenia andrei* (Earthworm) Mortality OECD TG 207 Laboratory/artificial soil conditions Nominal concentration

* No effects observed at the highest test concentration

Categorisation of environmental hazard

The categorisation of the environmental hazards of the assessed polymer according to the Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals (DCCEEW, 2022) or in the absence of data, based on worst case scenario is presented below:

Persistence

Not Persistent (Not P). Based on measured degradation study, the assessed polymer is categorised as Not Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on its high molecular weight, the assessed polymer is categorised as Not Bioaccumulative.

Toxicity

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

Environmental risk characterisation

The assessed polymer is not PBT and is hence unlikely to have unpredictable long-term effects (EPHC 2009).

A Risk Quotient (PEC/PNEC) for the aquatic compartment was not calculated as the assessed polymer will be imported into Australia for use as an antioxidant additive in plastics and exposure is expected to be minimal. The assessed polymer is not expected to be harmful to aquatic life or earthworms. On the basis of low hazard and limited exposure from the assessed use, the assessed polymer is not expected to pose significant risk to the aquatic environment. As such, the risk from the introduction of the assessed polymer can be managed.

References

DCCEEW (2022) Australian Environmental Criteria for Persistent, Bioaccumulative and/or Toxic Chemicals, DCCEEW.

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UNECE (United Nations Economic Commission for Europe) (2017). Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Seventh Revised Edition.

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