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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Hexanedioic acid, polymer with 1,2-propanediol, octyl ester

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment.

This Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1906	BASF Australia Ltd	Hexanedioic acid, polymer with 1,2-propanediol, octyl ester	ND*	≤ 60 tonnes per annum	A component of PVC films

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Human health risk assessment
Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

Environmental risk assessment
On the basis of the reported use pattern and limited expected aquatic exposure, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself. However, these should be selected on the basis of all ingredients in the formulation.

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by containment, physical collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
  - the polymer has a number-average molecular weight of less than 1000;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from a component of PVC films , or is likely to change significantly;
  - the amount of polymer being introduced has increased, or is likely to increase, significantly;
  - the polymer has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

(Material) Safety Data Sheet
The (M)SDS of the notified polymer and products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
BASF Australia Ltd (ACN: 62 008 437 867)
Level 12, 28 Freshwater Place
SOUTHBANK VIC 3006

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1,000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: other names, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, manufacture/import volume, site of manufacture/reformulation and identity of manufacturer/recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
China, Taiwan, Europe, Switzerland, Japan, and Philippines.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Palamoll® 638

CAS NUMBER
82904-80-1

CHEMICAL NAME
Hexanedioic acid, polymer with 1,2-propanediol, octyl ester

MOLECULAR FORMULA
$C_8H_{18}O.\ x(C_6H_{10}O_4.C_3H_8O_2)_x$

OTHER NAME(S)
Adipic acid polyester

MOLECULAR WEIGHT
Value for chemicals > 1,000 Da

ANALYTICAL DATA
Reference GPC spectra was provided.

3. COMPOSITION

DEGREE OF PURITY
> 95%

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
No losses by volatilisation, exudation or leaching are expected

DEGRADATION PRODUCTS
No degradation, decomposition or depolymerisation of the notified polymer is expected to occur under normal conditions of use.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Colourless liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Pour point: -9°C (M)SDS
Boiling Point	Not determined	Expected to decompose prior to boiling
Density	1,100 – 1,130 kg/m3 at 20°C	(M)SDS
Vapour Pressure	< 0.01 kPa at 20 °C	(M)SDS
Water Solubility	Low	(M)SDS
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities; however, not expected to rapidly hydrolyse under environmental conditions (pH 4-9) due to low water solubility
Partition Coefficient (n-octanol/water)	Not determined	Expected to be high based on low water solubility
Adsorption/Desorption	Not determined	Expected to adsorb to soil and sediment based on high molecular weight and low water solubility
Dissociation Constant	Not determined	Contains no dissociable functionalities
Flash Point	> 100°C	(M)SDS
Flammability	Not flammable	(M)SDS
Autoignition Temperature	430 °C	(M)SDS
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

Reactivity
The notified polymer is expected to be stable under normal conditions of use.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be introduced into Australia at approximately 100% concentration in 1,000 L intermediate bulk containers (IBC).

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1 – 10	10 – 30	10 – 30	30 – 50	30 – 60

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
BASF Australia Ltd

TRANSPORTATION AND PACKAGING
The notified polymer will be imported by sea in IBC containers and then transported by road in a shipping container to a third party contacted warehouse. This will be stored until required for delivery by road to a customer in Victoria.

USE
The notified polymer will be used as a plasticiser/softener in polyvinyl chloride (PVC) films at concentrations of up to 10%. The films containing the notified chemical will be used as cling wrap for food.

OPERATION DESCRIPTION
The IBC containing the notified polymer will be attached to a mixing vessel which can hold up to 80 litres of liquid. Contents from the mixing vessel will then be pumped into a sealed mixer which blends different components together with PVC resin to form the feedstock material for pelletising and manufacturing PVC beads. The beads will be used as feedstock to manufacture PVC film (containing up 10% of the notified polymer) *via* a blown film extrusion process.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Store personnel	10 – 15 mins/day	40
Batching operators	8 hours/day	40

EXPOSURE DETAILS
Worker exposure to the notified polymer in neat form during the importation, transport and storage is not expected, except in the unlikely event of an accident where the packaging may be breached or a spill occurred.

Dermal and ocular exposure to the notified polymer at concentrations up to 100% may occur during connection of the imported IBC to the mixing vessel and equipment cleaning processes. Exposure is expected to be minimized through the use of automated and enclosed systems and the use of personal protective equipment (PPE) such as eye protection and protective clothing. .

Inhalation exposure to the notified polymer is not expected to occur during the occupational use scenarios. However, the use of local exhaust ventilation in the workplace will minimise any exposure that does occur.

Workers may have dermal contact with PVC beads and film containing the notified polymer at up to 10% concentration. However, the notified polymer will have reacted into the polymer matrix and will not be available for exposure.

6.1.2. Public Exposure
The notified polymer will be for industrial use only, and will not be sold to the public. Direct exposure is not expected.

Members of the public may make contact with direct food contact materials (cling wrap) containing the notified polymer at < 10% concentration; however, significant exposure as a result of casual contact during handling is not expected as the notified polymer is expected to be incorporated in the polymer matrix. The notified polymer is listed in the EU food contact regulations (Annex I, Table 1 of Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food and/or amendments) and complies in regards to its composition and migration properties with a limit of 30 mg/kg.

6.2. Human Health Effects Assessment

No toxicity data were submitted.

The notified polymer has a high molecular weight (> 1,000 Da) and a low percentage (< 7%) of low molecular weight species < 1,000 Da; hence absorption across biological membranes is expected to be limited.

Health hazard classification
As no toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified polymer has the potential to be an eye irritant due to the presence of a relevant structural alert. However, the risk of irritation effects from exposure to the notified polymer may be limited by the high molecular weight (> 1,000 Da) and low percentage (< 7%) of low molecular weight species < 1000 Da.

During reformulation, workers may be exposed to the neat notified polymer. Given the high molecular weight and low percentage of low molecular weight species limiting dermal absorption, the potential risk of systemic toxicity is expected to be low. Once incorporated into PVC products, the notified polymer will be bound within the polymer matrix and exposure is not expected. Therefore, the risk to workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health
The notified polymer will not be available to the public.

The public may come into contact with the finished products containing the notified polymer at < 10% concentration. However, once incorporated into PVC film, the notified polymer will be bound into a polymer matrix and will not be bioavailable. Therefore, the risk to the public is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified polymer will be imported neat into Australia for reformulation into master batch pellets for the manufacture of PVC films. There is unlikely to be any significant release to the environment from transport and storage, except in the case of accidental spills and leaks. In the event of spills, the notified polymer is expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations.

During reformulation, the notified polymer will be blended with PVC resin to form master batch pellets. The reformulation process will involve blending operations that will be highly automated, and is expected to occur within a fully enclosed environment. Therefore, significant release of the notified polymer from this process to the environment is not expected. Wastes containing the notified polymer generated during reformulation include, empty import containers, and spilt materials. Wastes are expected to be collected and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE
Master batch pellets containing the notified polymer will be blown into PVC film using a blown film extrusion process. Wastes from this process will be in the form of solid master batch pellets or as manufactured PVC films. Wastes are expected to be recycled into the film manufacturing process, or collected and disposed of to landfill in accordance with local government regulations. No release of the articles containing the notified polymer to sewer is anticipated from use.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified polymer will be incorporated into an inert polymer matrix once the PVC films are blown. The notified polymer is expected to share the fate of the films, which are expected to be disposed of to landfill at the end of their useful lives.

7.1.2. Environmental Fate

The majority of the notified polymer will be bound within an inert polymer matrix and share the fate of PVC films. Therefore, the notified polymer in this form is not expected to be mobile or bioavailable. Based on the results of a ready biodegradability study, the notified polymer is considered readily biodegradable (87% in 28 days). For details of the environmental fate study, please refer to Appendix C. The notified polymer is not expected to bioaccumulate due to its high molecular weight, low water solubility and ready biodegradability. In landfill, the notified polymer is expected to degrade through biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated, as significant release of the notified polymer to the aquatic environment is not expected based on its reported use pattern as a plasticiser in PVC films.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Daphnia Toxicity	48 h EL50 > 100.2 mg/L (WAF*)	Not expected to be harmful to aquatic invertebrates
Algal Toxicity	72 h E_rL50 > 99.7 mg/L (WAF*)	Not expected to be harmful to algae

* Water Accommodated Fraction

Based on the above ecotoxicological endpoints for the notified polymer, it is not expected to be harmful to aquatic life. Therefore, the notified polymer is not formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has not been calculated, as the notified polymer is not expected to be harmful to aquatic life, and no significant aquatic release is expected from the reported use pattern.

7.3. Environmental Risk Assessment

A Risk Quotient (RQ = PEC/PNEC) has not been calculated, as no significant release of the notified polymer to the environment is expected from the proposed use pattern. The notified polymer is considered readily biodegradable, and is expected to have a low potential for bioaccumulation. On the basis of the assessed use pattern as a plasticiser in PVC films and the expected limited aquatic release, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 301 B Ready Biodegradability: CO2 Evolution Test.
Inoculum	Activated sludge from a domestic wastewater treatment plant
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Theoretical Carbon Dioxide ($ThCO_2$)
Remarks - Method	No significant deviation in protocol was reported.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
7	42	7	53
14	85	14	81
22	89	22	87
28	87	28	89

Remarks - Results	The dissolved inorganic carbon in the control was slightly higher than the < 0.5 mg/L criterion (0.7 mg/L); however, this was not deemed to have had a significant impact on the validity or the integrity of the study. All other validity criteria for the test were met and satisfied. The percentage degradation of the reference compound surpassed the threshold level of 60% by 8 days (61%) and reached 89% degradation by 28 days. Therefore, the test indicates the suitability of the inoculums. The test substance attained 89% degradation by 28 days, and attained the threshold level of 60% within the 10-day window. Therefore, the test substance is considered to be readily biodegradable according to the OECD (301 B) guideline.
CONCLUSION	The notified polymer is readily biodegradable.
TEST FACILITY	BASF (2008a)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified polymer
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	2.2-3.2 mmol Ca^{2+} + Mg^{2+}/L
Analytical Monitoring	None
Remarks - Method	The test substance was prepared as a Water Accommodated Fraction (WAF) due to its low water solubility. A stock solution with a nominal loading rate of 100.2 mg/L was prepared by stirring the test substance in water for 1 day, and any undissolved material was removed. A total of 20 daphnids were used. No significant deviation in protocol was reported.

RESULTS

Nominal Concentration mg/L	*Number of D. magna*	*Cumulative Immobilised (%)*	
		24 h	*48 h*
Control	20	0	0
100.2	20	0	0

EL50	> 100.2 mg/L at 48 hours (WAF)
NOEL	100.2 mg/L at 48 hours (WAF)
Remarks - Results	All validity criteria for the test were satisfied. The test solutions were not renewed during the 48 h test period. The 48 h EL50 and NOEL for *Daphnia* were determined to be > 100.2 mg/L and 100.2 mg/L (WAF), respectively, based on nominal loading concentrations.

CONCLUSION The notified polymer is not expected to be harmful to aquatic invertebrates.

TEST FACILITY BASF (2008b)

C.2.2. Algal growth inhibition test

TEST SUBSTANCE Notified polymer

METHOD OECD TG 201 Freshwater Alga and Cyanobacteria, Growth Inhibition Test.

Species	*Desmodesmus subspicatus* (green alga)
Exposure Period	72 hours
Concentration Range	Nominal: 0-100 mg/L Actual: Not determined
Auxiliary Solvent	None
Water Hardness	0.24 mmol Ca + Mg/L
Analytical Monitoring	None
Remarks - Method	The test substance was prepared as a Water Accommodated Fraction (WAF) due to its low water solubility. A stock solution with a nominal loading rate of 110.8 mg/L was prepared by stirring the test substance in water for 1 day, and any undissolved material was removed. After the addition of the inoculum culture, the loading rate of the test substance was calculated to be 99.7 mg/L. No significant deviation in protocol was reported.

RESULTS

Biomass		*Growth*	
E_bL50 mg/L at 72 h	*NOEL mg/L*	*E_rL50 mg/L at 72 h*	*NOEL mg/L*
> 99.7	99.7	> 99.7	99.7

Remarks - Results	All validity criteria for the test were satisfied. The actual concentrations of the test substance were at 0 and 72 hours within the 72 h test period. The test solutions were not renewed during the 72 h test period. The 72 h E_rL50, E_bL50 were both determined to be > 99.7mg/L (WAF), based on nominal loading concentrations. The 72 h NOEL was determined to be 99.7 mg/L (WAF).

CONCLUSION The notified polymer is not expected to be harmful to algae.

TEST FACILITY BASF (2008c)

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