File No PLC/485

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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polymer in CYDROTHANE® HP-1035

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Director
NICNAS

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SELF ASSESSMENT REPORT

Polymer in CYDROTHANE® HP-1035

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Cyetc Australia Holdings Pty Ltd (ABN 45 081 148 629)
Suite 1, Level 1 Norwest Quay
21 Solent Circuit
Norwest Business Park
Baulkham Hills NSW 2153

NOTIFICATION CATEGORY
LRCC: Synthetic Polymer of Low Concern

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

- Chemical identity information
- Molecular weight data
- Charge Density
- Import Volume
- Site of manufacture and or reformulation
- Purity

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US EPA: PMN No: TS62K59E

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
CYDROTHANE® HP 1035
CYDROTHANE® HA-711
CYDROTHANE® HA-721
CYDROTHANE® Polyurethane dispersions

PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met (yes/no/not applicable)*
Meets Molecular Weight Requirements	Yes
Meets Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
No Substantial Degradability	Yes
Not Water Absorbing	Yes
Low Concentrations of Residual Monomers	Yes
Not a Hazardous Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. INTRODUCTION AND USE INFORMATION

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

The chemical will be imported in 200 L polypropylene drums as an aqueous dispersion at a concentration of <40%

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1-2	1-2	1-2	1-2	1-2

USE

The notified polymer will be used as an adhesion promoter in the decorative surfaces. The notified polymer may also be used in laminating inks.

5. PROCESS AND RELEASE INFORMATION

5.2. Operation Description

The notified polymer will be imported into Australia as aqueous dispersion at a concentration of <40% in closed head 200 L polypropylene drums. It will be transported from the wharf to the customer's warehouse by truck where it will be stored before use.

Use in adhesive

At the end-users site a drum containing the notified polymer is manually installed into a dispensing machine. A suction tube is inserted into the drum through a small opening at the top of the 200 L drum. The system is closed, and the notified polymer is suctioned into the dispensing equipment, where it is dispensed onto the plastic substrate. The dispensing equipment is fully enclosed and automated. Any residue left in the drum is poured into the next drum to be used.

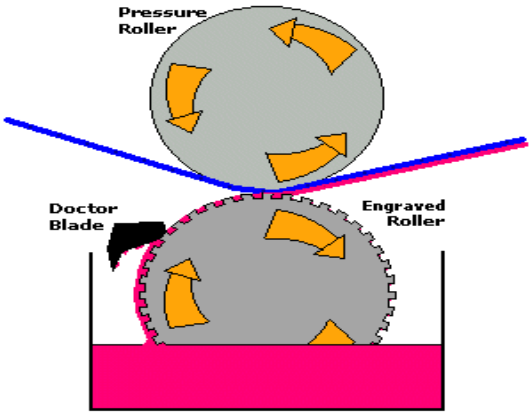
Ink Manufacture

The manufacture of the laminating inks will involve, formulation of the notified polymer into laminating ink by transfer of notified polymer by metered dosing to mixing vessel and mixing the notified polymer and other ingredients (such as, pigments, additives, solvents) in a sealed vessel fitted with a high-speed mixer and local ventilation system. The finished product is fed by gravity or pumped from the mill into 20 L plastic containers. The closed containers are manually put on pallets and then taken by forklift to the warehouse for storage and distribution.

Application of laminating inks

The end users for the laminating ink are likely to be packaging manufacturers. The ink is decanted manually from the 20 L plastic pail into an ink reservoir below the laminating machine rollers. The ink is applied by the gravure coating process (see below) where two polymer films are laminated together with the ink between the films. Following completion of a run, unused ink in the printing machine tray or reservoir is transferred back to ink container for reuse at a later time.

The printing machines are dedicated and thus require infrequent cleaning (twice per year). Cleaning is done by flushing the machinery with a suitable solvent. The solvent is collected and disposed of to a liquid waste treatment facility by a waste contractor.



6. EXPOSURE INFORMATION

6.1. Summary of Occupational Exposure

Number and Category of Workers			
Category of Worker	*Number*	*Exposure Duration Hours/Day*	*Exposure Frequency*
Storeman	1-3	8	48 weeks/year
Transport	≤5	2-4	30-60 days/year
End-use in adhesive			
Operator	1-3	8	48 weeks/year
Service Technicians	1-3	8	48 weeks/year
Ink Manufacture			
Ink manufacture/blending	30	4	100 days/year
Ink manufacture/filling	30	8	100 days/year
End-use in laminating inks			
Printing machine operators	10-15	6-8	50 days/year

Transport and warehousing

Workers are not expected to be exposed to the imported notified polymer, as they will be handling closed containers. The notified polymer will be supplied in 200 L drums and 20 L plastic pails and transported in secure pallets. Exposure is possible in the event of an accident where the packaging is breached.

Laminating Ink Manufacture

The notified polymer is an aqueous dispersion and as such dermal and ocular exposure is expected to be the main route of exposure. Incidental skin contact may occur during weighing and transfer of the polymer dispersant (containing <40% notified polymer) into the high speed mixer, and when filling the ink containers. The laminated ink will contain up to 15% of the notified polymer. Workers will wear chemical resistant gloves, coveralls and safety glasses when handling the notified polymer. The blending and filling operations are also conducted under local exhaust ventilation.

End-use in adhesive

The application process requires very little operator activity. Drums of the aqueous dispersion containing the notified polymer will be transferred from defined chemical storage areas to the manufacture area as required. Operators will manually install the drums into dispensing machine and insert a suction tube through a small opening at the top pail. The system is closed and the aqueous dispersion is delivered under vacuum to the dispensing equipment. The dispensing is carried out in fully automated and computer controlled equipment. This process is carried out under Local exhaust ventilation.

Operators are only exposed to notified polymer when replacing the empty drum with new drum. Any residue remaining in drum is poured into the next drum to be used. Lids are replaced on drums when

emptied. This activity occurs daily and takes approximately 5 minutes under normal conditions. Dermal and ocular exposure may occur during this activity, as a result of spills and drips. Workers involved in the process will wear gloves, overalls and safety glasses.

Cleaning and maintenance work
Cleaning of pump and transfer lines and maintenance work on the equipment used to dispense the aqueous emulsion containing the notified polymer is rarely required. Personnel undertaking maintenance tasks are required to wear gloves, overalls, safety glasses and a respirator if necessary.

End-use in Laminating Inks
The CYDROTHANE®1035 is present at a concentration of 10-25% (Occasionally the amount can reach 35%, (<15% notified polymer)) in the formulated ink product.

The laminating operators may be exposed to the product containing the notified polymer. The maximum potential exposure for laminating machine operators is estimated to be 6-8 hours per day, 50 days per year. The main routes for occupational exposure to the polymer will be through skin and eye contact. Laminating machinery operators will wear safety glasses, chemical resistant gloves, overalls and safety boots during transfer of the ink to printing machines, and cleaning of the machines. Printing machinery is fitted with exhaust ventilation ducts above the ink tray.

Workers handling the laminated material used for laminated film for packaging will not be exposed to the notified polymer because at this stage the notified polymer is unavailable for absorption.

6.2. Summary of Public Exposure
The notified polymer is intended only for use in industry.

The public is unlikely to be exposed to the notified polymer during transport, storage, and manufacture except in the accident of an accidental spillage.

When the notified polymer is used in laminating inks, it will enter the public domain in laminated film for packaging for various general items. Consequently, public contact to the packaging is likely to be high, but exposure to the notified polymer which is in the dried adhesive layer sandwiched between two layers of film is likely to be non significant.

6.3. Summary of Environmental Exposure
6.3.1. Environmental Release
RELEASE OF CHEMICAL AT SITE

Cytec Warehouse
The notified polymer will not be manufactured in Australia. Local operations will include transport and storage, formulation, filling and packaging and application by end-users (adhesion promoter in the decorative surfaces industry and laminating ink industry).

CYDROTHANE®1035 containing the notified polymer at <40% will be imported and stored in 200 L polypropylene drums. It will be transported from dockside by road to Cytec for storage. It will then be sold to ink manufacturers for formulation into laminating inks before it is sold to the laminating industry. The laminating inks will be packed in 20 L plastic bottle. CYDROTHANE ®1035 will also be sold to decorative surfaces industry for use as an adhesive on products such as laminates, cabinet doors and furniture.

Release at Cytec's site to the environment may result from accidental spills. It is estimated that a maximum of 1% of the notified polymer (20kg/year of notified polymer) would be lost during spillage. Spills are contained and soaked up with inert absorbent and placed in a sealable container and disposed of to landfill.

End-use as adhesive in products (e.g. laminates, cabinet doors, furniture)
Release of the polymer in the aqueous dispersion is only expected in the event of accidental spills/leaks and during transfer of 200 L polypropylene drums into the dispensing machinery. Spills will be limited to the capacity of the drums. It is estimated that a maximum of 1.5% of the notified polymer (~ 30 kg per annum) would be lost during spillage. Spill kits are in place in the storage and production areas.

Spills are collected with inert absorbent material and disposed of through a licensed waste disposal contractor. Spilled material will be collected with inert absorbent material and only trace amounts of material will remain. Flushing with water or with detergent will clean the area of spill and the waste material will go to a drain in the floor where it is collected in a pit. The pit is cleaned periodically and waste collected is sent off site for disposal by landfill by a licensed waste contractor.

If cleaning of the adhesive equipment is required, only small quantities of waste adhesive, typically less than 20 kg will be generated each time. This is collected for re-use if possible, or is disposed of through a waste disposal contractor for incineration. The equipment used to bond plastic substrates rarely requires cleaning.

Up to 3% residue will remain in the empty 200 L drums used in the adhesive industry, which is approximately 60 kg per annum (based on import levels of 2000 kg per annum). Residues remaining in the drums will be reused or disposed of by incineration. Empty drums will be collected by a licensed waste contractor and sent off-site for disposal.

Ink Manufacture

The ink formulation operations will take place at the ink manufacturing site. CYDROTHANE®1035 will be present in the laminating ink at a concentration of 10-25% (occasionally the amount can reach the 35% range). It is anticipated that there will be minimal release of the notified chemical during manual transfer from the storage containers to the mixers and during filling of ink into containers. Blending occurs in an enclosed system under exhaust ventilation and in a bunded area. Blending tanks or mixers are cleaned with suitable solvent. Release to environment during blending is expected to be 1% of import volume (up to 20 kg/year of notified polymer).

Up to 3% residue will remain in the empty 200 L drums used in formulation industry, which is approximately 60 kg per annum (based on import levels of 2000 kg per annum). Residues remaining in the drums will be reused or disposed of by incineration. Empty drums will be collected by a licensed waste contractor and sent off-site for disposal.

Laminating ink application

During the laminating process approximately 1% of notified polymer in aqueous dispersion may remain as residue on machinery and the adhesive tray. These residues will be wiped off with rags dampened with water and disposed of with industrial waste. The waste will then be disposed of to landfill by licensed waste contractors. Approximately 20 kg of polymer aqueous dispersion will go to landfill by this route.

At the end of each laminating run, any unused ink will be transferred back to pails for reuse. Pails containing residual polymer in aqueous dispersion (approx 100 mL/pail) will be disposed of to landfill. The majority of the residue will have dried to a solid mass by the time the empty pails reach landfill. Based on the maximum import rate of 2000 kg per annum, < 10 kg of the notified polymer per annum will go to landfill from this route.

RELEASE OF CHEMICAL FROM USE

No release of the notified polymer is anticipated once the adhesive is cured and incorporated in the plastic substrates. Plastic articles are most likely to end up in landfill at the end of their useful life.

The CYDROTHANE®1035 will be present in the laminating ink at a concentration of 10-25% (occasionally the amount can reach the 35% range). When used as laminating ink, the majority of the notified polymer will share the fate of the laminated substrate (e.g. packaging material) to which it is adhered. Used packaging material will mainly be disposed of to landfill. But some may be incinerated. Laminated film materials are not suitable for recycling. Thus, the life cycle for the notified polymer is not likely to involve recycling.

6.3.2. Environmental Fate

Endpoint	*Result*	*Effects Observed?*
Assessment of Ready Biodegradability (Modified Sturm) OECD 301B	28.5%	no

The notified polymer was not readily biodegradable within a 28-day test period when exposed to microorganisms maintained in an aerobic, aqueous mineralised environment. The mean cumulative biodegradation of the test substance was 28.5% after the 28-days and did not meet the test criteria for ready biodegradability.

The notified polymer is not expected to cross biological membranes due to its high molecular weight, and as such should not bioaccumulate.

7. ESTABLISHMENT OF LOW PHYSICAL AND CHEMICAL HAZARD

Appearance at 20ºC and 101.3 kPa	Milky white mobile liquid
Melting Point/Glass Transition Temp	Not applicable, as it is a liquid.
Density	1043 kg/m^3
Water Solubility	Insoluble. Dispersible in water.
Dissociation Constant	Not determined. The notified polymer contains carboxylic acid groups which are expected to have pKa value of 3-4.
Particle Size	Not determined. The polymer will be imported in a liquid dispersion.
Reactivity	Stable under normal conditions. The notified polymer is not expected to polymerise.
Degradation Products	Thermal decomposition or combustion may produce carbon monoxide, carbon dioxide and/or nitrogen oxides.

7.1. Comments

CYDROTHANE® polyurethane Dispersions are fully reacted, high molecular weight polymers that are dispersed in water by neutralizing the ionic groups in the backbone. There are no unreacted isocyanate groups.

8. ESTABLISHMENT OF LOW HUMAN HAZARD

8.1. Toxicology

The following toxicological studies were submitted for the notified polymer CYDROTHANE®HP-1035.

Endpoint	*Result*	*Classified?*	*Effects Observed?*
Rat, acute oral	LD50 > 5000 mg/kg bw	no	no
Rabbit, skin irritation	Non-irritating	no	no
Rabbit, eye irritation	Slight-irritating	no	yes
Skin sensitisation – Mouse Ear Swelling	Non-sensitising	no	no

*The Material Safety Data Sheet (MSDS) for CYDROTHANE®HP-1035 Polyurethane Dispersion contains references to rabbit acute dermal toxicity, rat acute inhalation toxicity and sensitisation by inhalation. However, the values for these studies are estimates. No actual test data are available on these endpoints for the notified polymer.

8.1.1 Discussion of Observed Effects

Eye Irritation: Unwashed: There was no corneal opacity or iritis noted at any observation period. Conjunctival irritation, noted in 3/3 eyes, cleared by day 2.
Washed: One eye appeared normal at each observation period. Conjunctival irritation, noted in two eyes, cleared by day 1.

8.2. Human Health Hazard Assessment

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by the low acute oral toxicity, non-irritation to skin, slight irritation to the eye and non-sensitising potential in the mouse ear swelling assay.

9. ENVIRONMENTAL HAZARDS

9.1. Ecotoxicology

The following ecotoxicological studies were submitted for the notified polymer CYDROTHANE®HP-1035

Endpoint	*Result*	*Effects Observed?*
Fish Toxicity (OECD 203)	LC50 > 100 mg/L	no
Daphnia Toxicity (OECD 202)	EC50 632 mg/L	no

9.1.1 Discussion of Observed Effects

In Rainbow Trout *(Oncorhynchus mykiss)* the 96-hour LC_{50} could not be calculated due to the lack of significant mortality at the specified time, and therefore can be stated to be > 100 mg wm/L. The no-observable-effect concentration (NOEC) was 100 mg wm/L based on the lack of significant mortality and sublethal effects at this test concentration.

In Water Flea *(Daphnia magna)* the 48-hour EC50 was calculated to be 632 mg wm/L (based on nominal concentrations) with 95% confidence limits of 454 and 881 mg wm/L. The no-observable – effect concentration (NOEC) was 160 mg wm/L.

9.2. Environmental Hazard Assessment

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by the low toxicity observed in the studies with fish, daphnia and ready biodegradation study.

10. RISK ASSESSMENT

10.1. Environment

The notified polymer is a component in an imported ready to use adhesive. Application of the adhesive to the substrate takes place in enclosed equipment and hence, environmental release of aqueous dispersion containing the notified polymer is expected to be minimal during product manufacture. It is estimated that approximately 180 kg per annum of waste polymer will be generated from accidental spills, equipment cleaning and as residues in empty containers.

The product containing the notified polymer reacts to form an inert solid. Thus, polymer wastes are expected to be disposed of in landfill as cured adhesive, in which case the polymer will be incorporated into the inert matrix and unavailable to the environment.

Most of the notified polymer will ultimately become incorporated into articles such as particle board and cabinet doors, where it will be unavailable to organisms. At the end of their useful lives, these articles would most likely be disposed of in landfill.

The notified polymer is also a component in laminating inks. CYDROTHANE®1035 will be present in the laminating ink at a concentration of 10-25% (occasionally the amount can reach the 35% range).

Release of the notified polymer to the environment is only likely in cases of spills. It is estimated that approximately 70 kg per annum of waste polymer will be generated from accidental spills, equipment cleaning and as residues in empty containers. However, the majority of the notified polymer will share the fate of the products in which it is incorporated and eventually be disposed of in landfill or incinerated.

10.2. Occupational health and safety

Use in Adhesive

The notified polymer is a slight eye irritant and worker exposure may occur during the manufacture of the finished product. Dermal and ocular exposure may occur as a result of drips and spills during the installation of drums in to the dispensing equipment and the transfer of residue adhesive in used drums to new drums leading to some risk of eye irritation. Exposure may also occur during the maintenance and cleaning of the manufacture equipment.

Worker exposure will be minimised by use of the appropriate personal protection equipment. When installing the drums and during maintenance work workers will wear eye protection, impermeable gloves and overalls, as required. Manufacture will occur in well ventilated areas, where local exhaust ventilation will be used.

Worker exposure during the transport, storage, and distribution of the imported notified polymer is unlikely to occur unless there is an accidental spillage or packaging breach.

Ink Manufacture

Workers involved in manufacturing the laminating ink will handle the notified polymer at concentrations of <40%. Exposure to the notified polymer may occur during the manufacturing stages. Exposure is most likely to occur from skin and eye contact with the notified polymer as it is incorporated during ink manufacture, and from exposure to inks that contain the notified polymer at up to 12.6%. Therefore there is some risk of eye irritation. Exposure and any potential for skin and eye contact during formulation is reduced by the presence of engineering controls, such as closed systems and a requirement for workers to wear personal protective equipment, such as impervious gloves, overalls and eye protection

Use in laminating inks

CYDROTHANE®1035 will be present in the laminating ink at a concentration of 10-25% (occasionally the amount can reach the 35% range).

During laminating process, dermal exposure to the polymer in CYDROTHANE®HP-1035 may occur during the transfer of CYDROTHANE®HP-1035 from pails to laminating machines and when cleaning the laminating equipment. The predominant routes of exposure during these activities are via skin and eye contact. Therefore, as the notified polymer is a slight eye irritant, there is some risk of eye irritation. Laminating machine operators wear safety glasses, chemical resistant gloves, overalls and safety boots when handling CYDROTHANE®HP-1035. Local exhaust ventilation further minimises exposure. Engineering controls and protective clothing combined are adequate to minimise the heath to laminating machine operators.

The notified polymer becomes unavailable for absorption once it is incorporated in the laminated material. Therefore, the health risk for workers handling laminated products is considered to be negligible.

There is little potential for significant health risk to the notified polymer in the transport and storage of the product containing this polymer.

10.3. Public health

It is expected that public exposure to the notified polymer in its liquid state will be limited, except in the rare event of an accidental spill. The notified polymer will be encapsulated within an inert, high molecular weight film, rendering it biologically unavailable. Public contact with the notified polymer in finished products (e.g. decorative articles or packaging items) is further limited as the adhesive containing the notified polymer is sandwiched between two layers of the polymer film, restricting any dermal contact.

11. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

11.1. Environmental risk assessment

The polymer is not considered to pose a risk to the environment based on its reported use pattern.

11.2. Human health risk assessment

11.2.1. Occupational health and safety

There is low concern to occupational health and safety under the conditions of the occupational settings described.

11.2.2. Public health

There is Negligible Concern to public health when used as an adhesive and in laminating inks.

12. MATERIAL SAFETY DATA SHEET

12.1. Material Safety Data Sheet

The notifier has provided MSDS in accordance with the schedule item B 12 of the *ICNA Act*. The accuracy of the information on the MSDS remains the responsibility of the applicant.

13. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced:
  - Local exhaust ventilation

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced:
  - Prevent spills and splashes
  - Lids should be replaced immediately on empty drums
  - NOHSC Exposure Standards for all components of the final product should not be exceeded in the workplace

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
  - Chemical resistant gloves, protective clothing and safety goggles/glasses.

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

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of to landfill or incinerated according to State and local government regulations.

Emergency procedures

- Spills/release of the notified polymer should be handled by absorbing with inert material and collection into a sealed container for disposal.