File No: PLC/82

November 1998

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Hexanedioic acid, polymer with 1,4-butanediol, 1,3-propanediol, 2,2-dimethyl and *iso*nonanol

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Hexanedioic acid, polymer with 1,4-butanediol, 1,3-propanediol, 2,2-dimethyl and *iso*nonanol

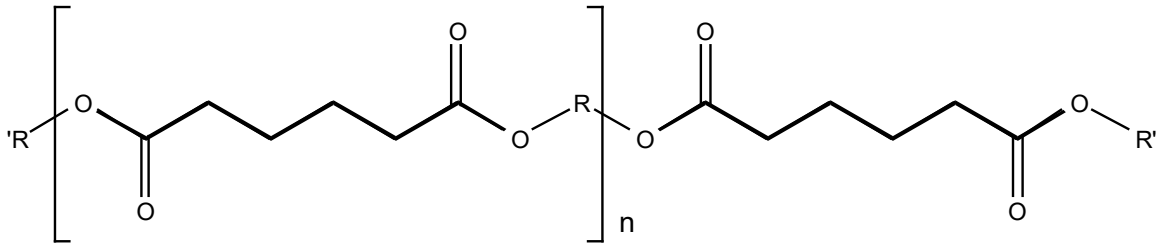
1. APPLICANT

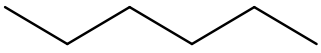
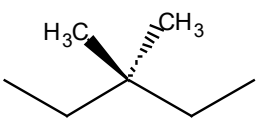
BASF Australia Ltd of 500 Princes Highway, NOBLE PARK VIC 3174 has submitted a limited notification statement in support of their application for an assessment certificate for hexanedioic acid, polymer with 1,4-butanediol, 1,3-propanediol, 2,2-dimethyl and *iso*nonanol as a synthetic polymer of low concern.

2. IDENTITY OF THE CHEMICAL

Chemical Name:	hexanedioic acid, polymer with 1,4-butanediol, 1,3-propanediol, 2,2-dimethyl and *iso*nonanol
Chemical Abstracts Service (CAS) Registry No.:	not assigned
Other Names:	adipic acid, polymer with 1,4-butanediol, neopentyl glycol and *iso*nonanol
Trade Name:	Palamoll 654, Palamoll 656
Molecular Formula:	$(C_6H_{10}O_4)_a.(C_4H_{10}O_2)_b.(C_5H_{12}O_2)_c.(C_9H_{20}O)_d$

Structural Formula:



R =  or 

R' = C_9H_{19}

Number-Average Molecular Weight (NAMW):	Palamoll 654 – 2894 Palamoll 656 – 3194
Weight-Average Molecular Weight:	Palamoll 654 – 5274 Palamoll 656 – 6396
Maximum Percentage of Low Molecular Weight Species	
Molecular Weight < 500:	1.0 %
Molecular Weight < 1 000:	5.8 %

Weight Percentage of Ingredients:

Chemical Name	*CAS No.*	*Weight %*
1,6-hexanedioic acid	124-04-9	56 %
1,4-butanediol	110-63-4	19 %
1,3-propanediol, 2,2-dimethyl	126-30-7	15 %
*iso*nonanol	27458-94-2	10 %

Method of Detection and Determination:	IR spectroscopy
Spectral Data:	IR 3451, 2959, 2874, 1737, 1462, 1420, 1380, 1244, 1172, 1078, 1001, 948, 752 cm^{-1}

Acceptance as Synthetic Polymer of Low Concern

The notified chemical is accepted as a Polymer of Low Concern, as all of the criteria for this classification are satisfied except that the worst case concentration of molecular weight species below 1000 is slightly above the cutoff level, and the water solubility is significantly above the required level. On the basis of the hazards associated with the notified polymer, these deviations are considered to be acceptable.

Number-Average Molecular Weight (NAMW):	> 1000, see above
Maximum Percentage of Low Molecular Weight Species	
Molecular Weight < 500:	
Molecular Weight < 1 000:	see above
Polymer Stability	the polymer is likely to be stable under normal environmental conditions
Reactivity	the polymer does not contain any reactive functional groups

Residual Monomer Concentration	All residual monomers are present at levels below those that would lead to the classification of the polymer as a hazardous substance
Particle Size	the notified polymer is liquid at room temperature
Charge Density	The polymer will not be charged under normal environmental conditions
Water Solubility	5.9 mg/L

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	clear, slightly yellowish viscous liquid
Pour Point:	Palamoll 654: -25°C Palamoll 656: -10°C
Specific Gravity:	Palamoll 654: 1.075 – 1.082 Palamoll 656: 1.085 – 1.105
Flash Point:	Palamoll 654: 288°C Palamoll 656: 274°C
Autoignition Temperature:	Palamoll 654: 400°C Palamoll 656: 425°C
Explosive Properties:	no explosive properties are expected

Comments on Physico-Chemical Properties

The polymer contains ester linkages which could potentially hydrolyse in the environmental pH range, particularly under alkaline conditions. However, hydrolysis is not expected within the environmental pH range (4-9) due to the low water solubility of the polymer.

4. PURITY OF THE CHEMICAL

Degree of Purity: not determined

Maximum Content of Residual Monomers:

Chemical Name	*CAS No.*	*Weight %*

1,6-hexanedioic acid	124-04-9	< 0.05 %
1,4-butanediol	110-63-4	< 0.05 %
1,3-propanediol, 2,2-dimethyl	126-30-7	< 0.05 %
*iso*nonanol	27458-94-2	< 0.3 %

5. USE, VOLUME AND FORMULATION

The notified polymer in the form of the products Palamoll 654 and Palamoll 656 will be used as plasticisers in flexible PVC formulations. It is expected to provide good resistance to extraction by oils, fats and water; also low volatility, low migration tendency and good thermal stability. PVC containing the notified chemical will be used in the wire and cable, building and automotive industries. Palamoll 654 is recommended for hoses, films, oil-resistant cables, dashboard coatings and electro-insulating films. Palamoll 656 is promoted for oil and hydrocarbon resistance and is recommended for hoses, films and oil-resistant cables. The formulation differences are not stated by the notifier.

It is expected that up to 200 tonnes of the notified polymer will be imported per annum for the first 5 years.

Palamoll 654 and Palamoll 656 will not be manufactured in Australia. They will be imported as neat liquids and will be blended with other PVC additives and thermal stabilisers, then blended with PVC resin at two customer sites. The final PVC blend will contain from 1 % to 50 % of the notified polymer. The finished PVC material will be pelletised for sale to article manufacturers.

6. OCCUPATIONAL EXPOSURE

Routes of Exposure
The notified chemical is a viscous liquid with an extremely low vapour pressure. The production processes are unlikely to produce aerosols. The most probable route of exposure to this polymer is dermal exposure to the neat liquid.

Transport and storage
The notified chemical will be imported in 200 L metal drums. Up to three transport drivers could be involved in transferring the drums to the warehouse, where up to three workers will be involved in transferring the drums onto trucks for transport as part of a mixed chemical load to the customer facility. Up to two store workers will transfer the drums to the store area and later to the production area. The waterside, transport and storage workers would only be exposed to the notified chemical in the event of an accident involving spillage of the notified chemical.

PVC Production
In the production area, up to fifteen production operators will be exposed to the notified chemical for up to 5-6 hours per shift, along with up to three maintenance workers. In the production area, Palamoll 654 or Palamoll 656 is removed from the drum using automatic dosing equipment. It is then weighed and mixed in a sealed blender with other additives and heat stabilising compounds. The additive mixture is transferred to a sealed extruder for

blending with PVC; the blend is then extruded, cooled and granulated before being packaged for storage and delivery to plastic products fabricators. Direct handling of the notified chemical is only likely in connecting transfer hoses for transfer from the imported drums to the blender, and for transfer of the additive blend to the extruder. Dermal exposure to drips and spills may be possible during these processes. Once the weighing and mixing have been completed, the notified chemical will be within a sealed automated system until it is formulated into the plastic pellets. In this form it will be immobilised within the polymer matrix.

The notifier states that local exhaust ventilation will be employed in the mixing area and anywhere that natural ventilation is considered inadequate. Exhaust ventilation in the region of the extruder can be expected as a minimum. The notifier further states that workers will wear appropriate industrial clothing conforming to Australian Standard AS 2919 (Standards Australia, 1987), with eye protection and gloves complying to the relevant Australian Standards being available if required. Respirators will also be available if required.

Laboratory
The notifier estimates that a maximum of three laboratory technicians (estimated exposure time 1-2 hours per shift) and five technical personnel (exposure time variable) would potentially be exposed to the notified chemical while conducting formulation trials. The exposure is likely to include manual handling of small amounts of the notified chemical using appropriate ventilation and protective equipment.

PVC Article Fabrication
The blended PVC pellets will be fabricated into a variety of articles which are likely to require several different methods of manufacture, such as extrusion and injection moulding. The notifier has not provided details of the manufacturing processes. The high molecular weight of the notified polymer indicates that it will not be volatile or otherwise mobile even with re-melting of the pellets in the further fabrication steps.

7. PUBLIC EXPOSURE

The notified polymer will be used in an industrial environment up to the stage where it is incorporated in a PVC polymer matrix and manufactured into articles such as wire and cable coatings, and building and automotive components.

Public exposure from the manufacture of plastic products is expected to be negligible. Spills resulting from the transport of the granulated plastic should not result in significant public exposure since the PVC matrix is not water soluble; any spills should be easily contained. Spills resulting from the transport of the notified polymer should also not result in significant public exposure, as the notified polymer has low water solubility. Spills are contained, soaked up in absorbent material and disposed to landfill in accordance with local regulations.

There will be minimal waste generated from the manufacture of plastic products as recycling is used extensively. Once the polymer is fixed in the PVC matrix it should not present a significant hazard. Public exposure from disposal is expected to be negligible.

Public contact with the notified polymer in the form of plastic coating on wires and cables,

and as building and automotive components is expected to occur. However, the polymer is a stable high molecular weight substance, and as such it is expected that it would be poorly absorbed across biological membranes. In addition, it is sealed in the polymer matrix.

8. ENVIRONMENTAL EXPOSURE

Release

Under normal conditions it is not expected that the chemical would be released during storage and transportation. The MSDS contains adequate instructions for handling a spill should one occur.

Release to the environment of the notified polymer as a result of manufacturing is expected to be minimal. Manufacturing takes place in a closed system, as detailed above. The notifier has estimated that a maximum of 1% of the notified polymer will remain in the import drums after emptying. This would account for a maximum of 2 tonnes of the notified polymer that will be disposed of by licensed drum recyclers during the cleaning of the drums for reuse.

At customer sites, it is anticipated that the PVC granules containing the notified polymer will be fed automatically into extrusion and moulding machinery from a hopper. Scrap will be either reworked through the process or put through the Cryogrind process and sold back to the manufacturer for reuse. Contaminated PVC scraps may be deposited into municipal landfills or incinerated. Overall, such waste streams would account for 0.5% of the annual import of the polymer (i.e. a maximum of 1 tonne per annum of waste polymer will be either recycled or deposited in landfill at the maximum rate of import).

Used articles containing the polymer will also eventually be deposited in landfills or incinerated.

Fate

The majority of the polymer is not expected to be released to the environment until it has been incorporated into PVC formulations. The end use products will either be deposited in landfill or incinerated at the end of their useful life. Due to the negligible solubility of the polymer, leaching from landfill is highly unlikely, and no movement from the landfill site is expected.

Any incineration of the notified polymer will result in the destruction of the polymer and produce oxides of carbon and water.

Biodegradation is unlikely. Biological membranes are not permeable to polymers of large molecular size and therefore bioaccumulation of the notified polymer is not expected (Gobas et al., 1986).

9. EVALUATION OF TOXICOLOGICAL DATA

No toxicology data were submitted, which is acceptable for a polymer of low concern. The polymer is stable with low volatility. Polymers of high molecular weights and low water solubility do not readily cross biological membranes. The notified chemical is currently in use in Europe in a similar way to the proposed Australian use. No observations of health problems or adverse symptoms have been reported.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided which is acceptable for polymers of low concern.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Disposal of the notified polymer to landfill is unlikely to present a hazard to the environment as it will be incorporated within PVC granules or finished products. Neither bioconcentration or leaching of the polymer is anticipated, due to the high molecular weight of the polymer and its low solubility. Biodegradation of the PVC product is also considered unlikely. Incineration of the notified polymer will result in its destruction, producing oxides of carbon and water.

The low environmental exposure of the polymer as a result of the proposed use, together with its expected negligible environmental toxicity, indicate that the overall environmental hazard should be negligible.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

No toxicological data was available for assessment.

The notified chemical is a polyester, which is a class of chemicals considered to have low toxicity. The low volatility and low water solubility minimise the routes of exposure, and the high molecular weight of the polymer indicate that it will be poorly absorbed across biological membranes. The occupational exposure to this chemical will be limited to the stage of formulation into PVC. Once it is incorporated into plastic products, the notified chemical is designed to be difficult to extract, and should thus be considered immobilised.

The most probable occupational exposure to the notified chemical is skin contact with the neat liquid at the formulation stage. The likelihood of substantial absorption through the skin is low, and the overall toxicity of the polymer would be expected to be low. The concentration of residual monomers is very low, and exposure would not result in health effects on this basis. The neat liquid polymer has very low vapour pressure and the high viscosity reduces the risk of aerosol formation. The formation of dusts containing the notified polymer can only occur within the enclosed mixing system. Therefore, the notified polymer is not likely to pose an occupational health risk.

The notifier indicates that local exhaust ventilation will be provided over all extruders, and

elsewhere where natural ventilation is considered inadequate, and that workers will be provided with industrial clothing to comply with Australian Standard AS 2919 (Standards Australia, 1987). Eye protection, gloves and respirators complying with the appropriate Australian Standards are also stated to be available as required.

There is negligible potential for public exposure arising from transportation, manufacture of plastic products and disposal of the notified chemical. While there may be public contact with the polymer in the form of plastic products, it is unlikely to migrate from the polymer matrix and is also unlikely to cross biological membranes. Based on this information, the notified polymer is unlikely to pose a significant hazard to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to hexanedioic acid, polymer with 1,4-butanediol, 1,3-propanediol, 2,2-dimethyl and *iso*nonanol the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992);
- Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.2 (Standards Australia, 1990);
- Impermeable gloves or mittens should conform to AS 2161 (Standards Australia/Standards New Zealand, 1998);
- All occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);
- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

Gobas FAPC, Opperhuizen A & Hutzinger O (1986) Bioconcentration of hydrophobic chemicals in fish: relationship with membrane permeation. Environmental Toxicology and Chemistry, 5 : 637-646.

National Occupational Health and Safety Commission (1994) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Australian Government Publishing Service, Canberra.

Standards Australia (1987) Australian Standard 2919-1987, Industrial Clothing. Standards Association of Australia, Sydney.

Standards Australia (1990) Australian Standard 3765.2-1990, Clothing for Protection against Hazardous Chemicals Part 2 Limited protection against specific chemicals. Standards Association of Australia, Sydney.

Standards Australia (1994) Australian Standard 1336-1994, Eye protection in the Industrial Environment. Standards Association of Australia, Sydney.

Standards Australia/Standards New Zealand (1992) Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications. Standards Association of Australia/ Standards Association of New Zealand, Sydney/Wellington.

Standards Australia/Standards New Zealand (1994) Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear. Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

Standards Australia/Standards New Zealand (1998) Australian/New Zealand Standard 2161.2-1998, Occupational protective gloves, Part 2: General requirements. Standards Association of Australia, Sydney.