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NATIONAL INDUSTRIAL CHEMICALS
NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

# LEXAN SP

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Director
Chemicals Notification and Assessment

# FULL PUBLIC REPORT

# LEXAN SP

## 1. APPLICANT

General Electric Plastics (Australia) Pty Ltd, 175 Hammond Road, Dandenong, Victoria 3175.

## 2. IDENTITY OF THE CHEMICAL

**Trade name:** Lexan SP resin

**Other name:** Modified poly(ester-carbonate) resin

**Chemical Abstracts Service**

**(CAS) Registry No:** Not yet assigned

**Spectral data:** Infrared spectrum for Lexan SP was provided.

Based on the nature of the chemical and the data provided, Lexan SP is considered to be non-hazardous. Therefore, the following details have been exempted from publication: chemical name, molecular and structural formulae, number average molecular weight, import volume, process description, spectral data, weight percentage and ingredients and residual monomers.

## 3. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance:** white powder with slight odour. Supplied as pigmented pellets.

**Particle size:** powder - 150 to 1000 µm;
pellet - 2 to 5 mm diameter
(pellets may also contain a small amount of fines)

**Glass-transition temperature:** 126-128°C

| | |
|---|---|
| **Density:** | 1.18 x $10^3$ kg/$m^3$ |
| **Vapour Pressure:** | stated to be negligible, as expected for a polymer of this molecular weight. |
| **Water Solubility:** | 0.63 $mgL^{-1}$, using UV absorption spectrometry with a detection limit of 0.1 $mgL^{-1}$ |
| **Hydrolysis:** | test not conducted according to OECD guidelines in view of the substance's water insolubility. However, the substance has been shown to hydrolyse in extreme alkaline conditions (see below). |
| **Partition Co-efficient:** | not established given the polymer's water insolubility. |
| **Adsorption/Desorption:** | not established given the polymer's water insolubility. |
| **Dissociation Constant:** | not established given the polymer's water insolubility. |
| **Flammability:** | dust clouds may be ignited by a spark or flame source.<br>Combustion products may include carbon monoxide and carbon dioxide. |
| **Autoignition Temperature:** | estimated to be 630°C |
| **Explosive Properties:** | like most organic materials, an explosion may occur due to static discharge under dust cloud conditions. |
| **Reactivity/Stability:** | stable at ambient conditions; non-oxidising. |

**Degradation Products:** During thermal processing, the following fume components are generated:

| | |
|---|---|
| methylene chloride | 2 mg/kg resin |
| phenol | 5 mg/kg |
| diphenylcarbonate | 50 mg/kg |

**Comments on Physico-Chemical Properties:**

The water solubility data provided indicate that the polymer may be slightly soluble. However, given the method used (UV absorption spectrometry) and the presence of residual monomers, which are UV absorbers, the water solubility value for Lexan SP is likely to be significantly lower than that stated above.

No data were provided for hydrolysis and partition coefficient on the grounds that the polymer has low water solubility. Although the polymer may hydrolyse at the carbonate sites, the polymer's low water solubility would make this test difficult to perform. Hydrolysis has only been demonstrated in extreme alkaline conditions (no hydrolysis at 100°C overnight with 5% NaOH but hydrolysed with 25% NaOH under the same conditions) where bisphenol A was found to be the major hydrolytic product.

No data were provided for adsorption/desorption on the grounds that "due to the insoluble and inert nature of the material, adsorption/desorption in and from soils is not expected to occur". This argument is acceptable.

## 4. METHOD OF DETECTION AND DETERMINATION

Lexan SP can be identified by Infrared spectroscopy.

## 5. PURITY OF THE CHEMICAL

**Degree of purity**: >99%

**Toxic or hazardous impurities**:

. **Chemical name:** Methylene chloride
**Synonym**: Methane, dichloro-
**CAS No.**: 75-09-2
**Maximum residual**: 15 ppm
**Toxic properties**: low acute oral toxicity (LD50 rat = 1600 mg/kg); severe skin irritant (rabbit); moderate eye irritant (rabbit); (1)
National exposure standards (2):
TWA: 50 ppm
Category 3 Carcinogen

. **Chemical name:** Triethylamine
**Synonym**: N,N-diethylethanamine
**CAS No.**: 121-44-8
**Maximum residual**: 10 ppm
**Toxic properties**: moderate acute oral toxicity (LD50 rat = 460 mg/kg); mild skin irritant (rabbit) and severe eye irritant (rabbit); (1)
National Exposure standards (2):
TWA: 3 ppm
STEL: 5 ppm

## 6. INDUSTRIAL USES AND REFORMULATION

Lexan SP resin is to be imported into Australia, in approximately equal proportions, as both powder and pigmented-pellets. The powder will be reformulated in Australia, without major chemical conversion, to pigmented pellets by a process of mixing, blending, extrusion, pelletizing, sieving and packaging.

Lexan SP pellets will be distributed to approximately 20 customers located throughout Australia for the purposes of injection moulding and possibly extrusion. The broad process of injection moulding involves heating of pelleted resin in hoppers, injection of molten resin into moulding, water cooling of moulded product and release of product from mould. Lexan SP will be used for a range of products, including plastic cases for mobile phones and light diffusers.

## 7. PUBLIC AND OCCUPATIONAL EXPOSURE

Lexan SP powder will be imported in 44 lb multilayered paper bags and pellets will be imported and distributed in 55 lb

multilayered paper bags or 1000 lb plastic lined boxes. If demand is sufficient the powder may be imported in a tanker or shipping container for direct transfer to on-site storage silos. Exposure during storage and transport should be minimal under normal conditions.

Lexan SP will be fed into mixers either by conveyor from the silos or by workers manually handling the bags. Where Lexan SP is pneumatically conveyed from the silos to the production lines, dust is contained by filters and extraction systems. Dust hoods are provided at most de-bagging points where the chemical is manually handled.

Dust extractors are fitted to mixers and fume extractors are fitted to extruders. An extractor cannot be fitted to the blender/hopper, thus workers in this area will wear dust masks.

Lexan SP will be delivered to the consumers only in pellet form. A small amount of fines may be present. Fumes are produced during thermal processes. All work areas will be ventilated to allow dust and fume extraction.

The notifier states that workers who may be exposed to Lexan SP are required to wear protective clothing, including cotton overalls, neoprene gloves and dust masks.

Recycling will be the preferred method of disposal of Lexan SP. If recycling is not viable the waste will be disposed of to landfill or incinerated.

The public will only be exposed to the final moulded/extruded product.

## 8. ENVIRONMENTAL EXPOSURE

### 8.1 Release

Given that the substance is a solid and is considered inert and water insoluble, accidental spillages should be contained with minimal environmental exposure.

The company have estimated that 2.5% non-recyclable waste will be generated by the reformulation process. Given that no more than half of the import volume (expected to be up to 1000 tonnes) will be reformulated, the maximum total waste to be disposed of to

landfill will be 12.5 tonnes. Releases to the aquatic environment are not expected. The non-recyclable waste will be disposed of to landfill by BFT Waste Disposal Systems at Lyndhurst, Victoria. Liquid waste, which is expected to be minimal, is to be disposed of via Harpers Treatment Plant, Coburg, where water is treated and recovered and the organic matter incinerated.

Customers will use Lexan SP for injection moulding and possibly extrusion. Contamination of the cooling water is unlikely as such water does not come in contact with the moulded plastic but recirculates through the equipment to regulate the temperature. The notifier has indicated that customers, located throughout Australia, will recycle injection moulding "off-cuts" and, at the end of a production run, retain unused resin pellets by emptying the hopper into storage containers. It is expected that less than 1% of the resin pellets will be non-recyclable and disposed of to landfill. Given that there are expected to be 20 customers using a maximum total of 1000 tonnes of resin pellets, the expected amount of waste disposed of to each customer's landfill site will be in the order of 500 kg per annum.

### 8.2 Fate

The notifier states that by nature of its application and the inert nature of the finished product, the polymer is required to be stable under a wide range of conditions.

The polymer will form oxides of carbon, hydrocarbon fragments and water vapour on combustion.

The polymer is not expected to hydrolyse in landfill conditions and due to its water insolubility is unlikely to enter groundwater.

## 9. EVALUATION OF TOXICOLOGICAL DATA

### 9.1 Acute Toxicity

Toxicological studies have not been carried out with Lexan SP. However, the results of acute toxicity studies for other Lexan powders were provided by General Electric Plastics. One of the powders, Lexan powder 145-110, is a production powder similar to Lexan SP which contained no stabilizers or colourants.

### 9.1.1 Oral Toxicity (3)

Two male Charles River CD rats were each administered a single, 500 mg/kg dose of Lexan powder 145-110 contained within gelatin capsules. The rats were observed for mortality during the first four hours following administration and daily for 14 days. Both rats survived and their body weight gain was unaffected by treatment.

### 9.1.2 Oral Toxicity (4)

In a limit test, a 5 gm/kg dose of Lexan powder (140 grade, Lot G518Z) was administered by gavage, in 10% corn oil, to 10 Sprague-Dawley rats (5 males and 5 females). The rats were observed for signs of toxicity at 1, 3, 6, 24, 48, 72 hours and daily thereafter up to 14 days. All animals were killed after 14 days, and examined for gross pathological organ changes. No deaths, clinical signs of toxicity or gross pathological organ changes were observed. Piloerection was noted in 5 rats six hours after administration. All rats had returned to normal within 24 hours. Lexan powder had low acute toxicity under the conditions of the study.

### 9.1.3 Dermal Toxicity (3)

Four New Zealand White rabbits were divided into 2 groups, 1 male and 1 female in each group. One rabbit in each group received a 200 mg/kg dermal dose of Lexan powder 145-110, and the other rabbit received a 2000 mg/kg dose. The powder was applied under an occlusive wrap to the shaved backs of the rabbits. The skin of one rabbit in each group had also been abraded. The wraps were removed 24 hours after application and the sites wiped clean. The rabbits were observed for 14 days for mortality only. Bodyweights were recorded at dosing, and 7 and 14 days after dosing.

There was one death at 200 mg/kg which was attributed to colitis. Bodyweight gains appeared normal. However, OECD Guidelines (5) recommend that at least 5 animals should be used and at least 3 dose levels.

### 9.1.4 Skin Irritation (3)

A 500 mg dose of Lexan powder 145-110 was applied under an occlusive wrap to the shaved backs of two New Zealand White

rabbits, one male and one female. The skin of one rabbit had been abraded with a scalpel. The wraps were removed 24 hours after application. The skin was examined for signs of erythema and oedema immediately and 48 hours after removal of the wraps. Very slight erythema was noted in only one rabbit at 24 hours. The results of this study indicate that Lexan 145-110 powder was a very slight irritant in rabbits at the concentration tested. However, OECD Guidelines (6) recommend that at least 3 animals should be used for a study of this type.

### 9.1.5 Eye Irritation (3)

A 100 mg dose of Lexan powder 145-110 was instilled into the conjunctival sac of the right eye of two New Zealand White rabbits (1 female and 1 male). The left eye served as the untreated control for each rabbit and none of the eyes were washed. The eyes were examined with the aid of sodium fluorescein at 1, 24, 48 and 72 hours post instillation and were also scored for lesions using the Draize scale.

Slight/very slight chemosis, slight/moderate erythema and very slight corneal opacity were observed in the treated eyes from 1 to 48 hours. There was marked discharge from the treated eye of one rabbit at 1 hour. Both treated eyes had returned to normal within 72 hours. According to the Draize score, Lexan SP 145-110 was a moderate eye irritant in rabbits at the concentration tested. However, OECD Guidelines (7) recommend that at least 3 animals should be used for a study of this type.

### 9.1.6 Inhalation Toxicity (8)

Ten CD strain rats (5 females and 5 males) were exposed for six hours to fumes generated during the extrusion of plastic made from Lexan L-140-83-1 powder. 'Grab' samples determined that the average phenol concentration in the generated fumes was 2.22 $mg/m^3$ in an average air flow of 110 L/min. The animals were observed frequently during the exposure period, one hour after exposure and daily for 14 days. No animals died, no clinical signs of toxicity were observed and all animals gained weight during the study. Necropsy at the end of the 14 days revealed no gross organ changes.

## 9.2 Overall Assessment of Toxicological Data

No toxicity tests have been carried out with Lexan SP. However, toxicological studies with similar Lexan powders indicate low acute oral and dermal toxicity, moderate eye irritation and very slight skin irritation in test animals. The moderate eye irritancy of the Lexan powder may be the result of mechanical abrasion of the eye. Fumes generated during extrusion with Lexan powder did not result in significant toxicity in rats during a six hour exposure. Lexan SP is likely to have a similar acute toxicity profile.

During processing, methylene chloride and phenol may be generated. Methylene chloride produces nervous system effects in humans (9) and is suspected of having carcinogenic potential (Category 3) (2). Phenol produces severe tissue irritation and at high concentrations causes central nervous system depression in humans (10).

The polymer has a high molecular weight (>10,000) and is therefore unlikely to be absorbed across biological membranes, such as the skin and the gastrointestinal tract (11).

# 10. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Under normal conditions, public exposure to Lexan SP resin is not expected. The public will only be exposed to the final, inert moulded/extruded product.

Occupational exposure to Lexan SP is expected to be low because of its manner of use and disposal.

The polymer has a high molecular weight and is therefore unlikely to cross biological membranes. Based on the results of acute toxicity tests for similar polymers, Lexan SP is likely to have low acute and dermal toxicity and to be non irritating to the skin and a moderate eye irritant. As Lexan SP powder is a potential eye irritant, goggles should be worn by workers who may have direct contact with the powder. The percentage of residual monomers in Lexan SP is less than 0.1% and thus should not pose a significant risk to workers.

During thermal processing of Lexan SP, methylene chloride and phenol fumes are generated. To minimise worker exposure to these

substances, the workplace should be well ventilated and local exhaust ventilation fitted where fumes may be produced.

Therefore, due to its low exposure and apparent low toxicity, Lexan SP is unlikely to pose a significant health and safety hazard to the public and workers.

## 11. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provide, which is acceptable for polymers of NAMW > 1000.

## 12. ASSESSMENT OF ENVIRONMENTAL HAZARDS

The polymer is unlikely to present a hazard to the environment when incorporated into moulded products.

The Lexan SP is not expected to exhibit toxic characteristics because large polymers of this nature are not readily absorbed by biota.

The notifier indicates that wastes generated from resin powder reformulation to pigmented pellets will be no greater than 2.5% resulting in a maximum disposal volume to landfill of 12.5 tonnes per annum (total import volume of 1000 tonnes). the waste will be disposed of to a specified landfill.

Non-recyclable waste from the notifier's customers is not expected to exceed 1% resulting in an average annual disposal volume to landfill of 500 kg. The customers are located throughout Australia resulting in a wide distribution of the substance, as plastic products and as non-recyclable waste disposed of to landfill.

## 13. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for Lexan SP Resin is provided at Attachment 1. This MSDS was provided by General Electric Plastics (Australia) as part of their notification statement. They are reproduced here as a matter of record. The accuracy of this information remains the responsibility of General Electric Plastics (Australia).

## 14. RECOMMENDATIONS FOR THE CONTROL OF PUBLIC AND WORKER EXPOSURE AND ENVIRONMENTAL EXPOSURE

To minimise public and worker exposure to Lexan SP, the following guidelines and precautions should be observed:

. the workplace should be well ventilated and processing fumes removed through local exhaust ventilation;

. workers who may come into contact with Lexan SP should:

  - wear appropriate goggles when handling the powder;

  - wear dust masks when handling the powder; and

  - observe good personal hygiene practices.

. good housekeeping practices should be observed;

. disposal of Lexan SP should be in accordance with local regulations;

. generation of a dust cloud should be avoided; and

. a copy of the Material Safety Data Sheet should be readily accessible to employees.

## 15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of Lexan SP 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

1. U.S. National Institute for Occupational Safety and Health, *Registry of Toxic Effects of Chemical Substances* (RTECS).

2. National Occupational Health and Safety Commission, *Exposure Standards for Atmospheric Contaminants in the Occupational Environment*, Australian Government Publishing Service, Canberra, 1991.

3. *Acute Toxicity Screening Test Results - LEXAN Resin Powder*, International Research and Development Corporation. Data on file, General Electric (1978).

4. *The Single Dose, Acute Oral Toxicity of Lexan Resin (140 Grade, Lot G518Z) in Rats*, Cannon Laboratories, Inc. Data on file, General Electric (1978).

5. OECD Guidelines for Testing of Chemicals, TG 402 Acute Dermal Toxicity.

6. OECD Guidelines for Testing of Chemicals, TG 404 Acute Dermal Irritation/Corrosion.

7. OECD Guidelines for Testing of Chemicals, TG 405 Acute Eye Irritation/Corrosion.

8. Acute Inhalation Evaluation of L-140-83-1 Fumes in Rats, TPS Study No.: 191A-101-710-83. Data on file, General Electric, (1983).

9. IARC Monographs v. 41, 1986

10. IARC Monographs v. 47, 1989

11. United States Federal Register, 40 CFR Part 723, *Premanufacture Notification Exemptions; Exemptions for Polymers*, 1984.