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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

PUBLIC REPORT

Polymer in Figure 4 TOUGH-GRY 10

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 and Energy.

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**

TABLE OF CONTENTS

SUMMARY	3
CONCLUSIONS AND REGULATORY OBLIGATIONS	3
ASSESSMENT DETAILS	5
1. APPLICANT AND NOTIFICATION DETAILS	5
2. IDENTITY OF CHEMICAL	5
3. COMPOSITION	5
4. PHYSICAL AND CHEMICAL PROPERTIES	5
5. INTRODUCTION AND USE INFORMATION	6
6. HUMAN HEALTH IMPLICATIONS	7
6.1. Exposure Assessment	7
6.1.1. Occupational Exposure	7
6.1.2. Public Exposure	7
6.2. Human Health Effects Assessment	7
6.3. Human Health Risk Characterisation	8
6.3.1. Occupational Health and Safety	8
6.3.2. Public Health	8
7. ENVIRONMENTAL IMPLICATIONS	8
7.1. Environmental Exposure & Fate Assessment	8
7.1.1. Environmental Exposure	8
7.1.2. Environmental Fate	8
7.1.3. Predicted Environmental Concentration (PEC)	9
7.2. Environmental Effects Assessment	9
7.2.1. Predicted No-Effect Concentration	9
7.3. Environmental Risk Assessment	9
BIBLIOGRAPHY	10

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/2080	3D Systems Asia Pacific	Polymer in Figure 4 TOUGH-GRY 10	ND*	≤ 25 tonnes per annum	A component of industrial 3D printing formulation

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

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.

Human Health Risk Assessment

Provided that the recommended controls are being adhered to, 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, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

Health Surveillance

- As the notified polymer has the potential to be a skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of asthma or other allergic reactions.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following isolation controls to minimise occupational exposure to the notified polymer during its use:
 - Enclosed/automated processes
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling and use of the 3D printing formulation containing the notified polymer:
 - Avoid contact with skin and eyes
- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer during manual transfer and handling wet printed material:
 - Impervious gloves
 - Safety glasses or goggles
 - Respiratory protection if inhalation exposure may occur
 - Protective clothing

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

- A copy of the 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.

Emergency procedures

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

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.

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 g/mol;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of polymer has changed from a component of industrial 3D printing formulation, 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.

Safety Data Sheet

The 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 SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

3D Systems Asia Pacific (ABN: 32 060 673 396)
30-32 Ceylon Street
NUNAWADING VIC 3131

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1,000$ g/mol

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details exempt from publication include: chemical name, other names/specific other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Schedule data requirements are varied for all physical and chemical properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Figure 4 TOUGH-GRY 10 (containing the notified polymer at up to 40% concentration)

MOLECULAR WEIGHT

Number average molecular weight (M_n) is $> 1,000$ g/mol.

ANALYTICAL DATA

Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

$> 98\%$

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Grey dispersion

<i>Property</i>	<i>Value</i>	<i>Data Source/Justification</i>
Melting Point/Freezing Point	Not determined	Introduced as a dispersion and expected to be < 0 °C
Boiling Point	Not determined	Expected to decompose prior to boiling.
Density	1,100 kg/m ³ at 20 °C	SDS
Vapour Pressure	Not determined	Expected to be low due to the high molecular weight.
Water Solubility	Insoluble	SDS
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities but significant hydrolysis is not expected in the environmental pH range of 4-9
Partition Coefficient (n-octanol/water)	Not determined	May partition from water to n-octanol based on its insolubility in water

<i>Property</i>	<i>Value</i>	<i>Data Source/Justification</i>
Adsorption/Desorption	Not determined	Expected to have low mobility in soil based on its high molecular weight and insolubility in water
Dissociation Constant	Not determined	Contains no dissociable functionalities
Particle Size	Not determined	Introduced as a dispersion
Flash Point	Not determined	Introduced as a dispersion
Flammability	Not determined	Not expected to be highly flammable
Autoignition Temperature	Not determined	Not expected to undergo autoignition
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties

Reactivity

The notified polymer is expected to be stable under normal conditions of use. The polymer is UV-curable and may polymerise if exposed to direct sunlight.

Physical Hazard Classification

As no data were submitted the notified polymer cannot be 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 not be manufactured in Australia. The notified polymer will be imported into Australia as a component of photocurable formulation for 3D printing at $\leq 40\%$ concentration.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	5-25	5-25	5-25	5-25	5-25

PORT OF ENTRY

Melbourne

TRANSPORTATION AND PACKAGING

The notified polymer will be imported as a component of photocurable formulations for 3D printing in 1 kg sealed plastic bottles and will be transported by road or rail.

USE

The notified polymer will be used in 3D printing of plastic articles.

OPERATION DESCRIPTION

No reformulation or repackaging of the imported formulation containing the notified polymer will be carried out in Australia.

The formulation containing the notified polymer will be manually poured into a solution tray within the printer. Localised curing of the notified polymer and other components will be controlled by a laser shining through the tray. The printed part is then lifted out of the solution and the excess solution is allowed to drip back into the solution tray. Uncured material on the printed article will be removed by rinsing with solvent (isopropyl alcohol). A final UV-curing process is performed within a different chamber of the printer. Rinsates containing the notified polymer will be collected and sent off site for recycling.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and warehousing	2-4	12
Printer operators	8	200

EXPOSURE DETAILS

Transport and storage

Transport and storage workers may come into contact with the notified polymer as a component of the imported formulation at < 40% concentration only in the unlikely event of accidental rupture of the packaging.

Printer operators

Printer operators may experience dermal and ocular exposure to the notified polymer at < 40% concentration during manual transfer of the formulation containing it to the 3D printer and when cleaning the printer. According to the notifier, exposure to workers is expected to be minimised through the use of personal protective equipment (PPE) such as eye protection, and impervious gloves during manual transfer and cleaning, as well as the enclosed and automated processes during the printing operation. Inhalation exposure of workers to the polymer is not expected as the notified polymer is unlikely to form airborne vapour due to its high molecular weight.

6.1.2. Public Exposure

The formulation containing the notified polymer (at < 40% concentration) is intended for industrial use only and will not be available to the public. The public may have dermal contact with printed articles. However, the notified polymer will be strongly bound within the cured polymer matrix and will not be available for exposure.

6.2. Human Health Effects Assessment

No toxicity data were submitted.

Based on the high molecular weight (> 1,000 g/mol), expected low water solubility and low percentage of low molecular weight species < 1,000 g/mol, the notified polymer is not expected to be absorbed across biological membranes to a significant extent.

Irritation and sensitisation

No data were provided for the notified polymer on eye or skin irritation, or skin sensitisation.

The notified polymer contains methacrylate functional groups which are known to have potential to cause skin and eye irritation, and skin sensitisation (US EPA, 2010). The potential for the notified polymer to cause skin sensitisation may be reduced by the limited potential for the notified polymer to be dermally absorbed.

Mutagenicity/Genotoxicity

Results of a number of mutagenicity studies on acrylate and methacrylate compounds have been evaluated (Johannsen *et al.*, 2008). In general, it was found that these compounds were negative in bacterial reverse mutation assays and other *in vitro* mammalian point mutation assays. While some positive results were observed in *in vitro* mammalian clastogenicity assays, the results from *in vivo* assays were all negative. Therefore, based on the available information, the notified polymer is not likely to be genotoxic.

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.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Toxicological data were not provided for the notified polymer. The notified polymer may have the potential to cause irritation and sensitisation based on the presence of reactive functional groups. However, given the limited potential for dermal absorption, the potential for sensitisation effects is expected to be low.

Workers may be at risk of irritation or sensitisation from the notified polymer at < 40% concentration during manual transfer of the formulation containing it to the 3D printer and when cleaning the printer. The use of PPE such as overalls, impervious gloves and safety glasses should minimise the risk to workers.

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

6.3.2. Public Health

The formulation for 3D printing containing the notified polymer will not be sold to the public.

The public may have dermal contact with the formulation for 3D printing containing the notified polymer after they have been applied and cured. Once the formulation is cured and dried, the notified polymer will be bound within a polymer matrix and will not be available for exposure.

Therefore, the notified polymer when used as proposed is not considered to pose an unreasonable risk to public health.

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 into Australia in a photocurable formulation for 3D printing in sealed plastic bottles. No reformulation or repackaging of the imported formulation will occur in Australia. Accidental spillage of the formulation containing the notified polymer during import and transport are expected to be collected for disposal to landfill, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The 3D printing process will occur within an enclosed chamber in well ventilated area. The formulation containing the notified polymer will be manually poured into a solution tray within the printer. Localised curing of the notified polymer and other components will be controlled by a laser shining through the tray. The printed part is then lifted out of the solution and the excess solution is allowed to drip back into the solution tray. Uncured material on the printed article will be removed by rinsing with a solvent (isopropyl alcohol). Rinsates containing the notified polymer will be collected and sent off site for recycling by approved facilities. A final UV-curing process is performed within a different chamber of the printer. The notified polymer will then be fused within the polymer matrix to form a hard, solid structure.

RELEASE OF CHEMICAL FROM DISPOSAL

Empty bottles containing residual notified polymer will be disposed of to landfill in accordance with local government regulations. The 3D printed objects are also expected to be disposed of to landfill at the end of their useful lives.

7.1.2. Environmental Fate

No environmental fate data were submitted. Based on its use in 3D printing, most of the notified polymer is expected to share the fate of the printed 3D objects, which are expected to be disposed of to landfill at the end of their useful lives. In landfill, the notified polymer will be present as cured solids and will be neither bioavailable nor mobile. The notified polymer is expected to be slowly degraded by biotic and abiotic processes to form water, oxides of carbon and nitrogen. Therefore, release of the notified polymer to the aquatic environment will be limited based on the reported use pattern.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated as release of the notified polymer to the aquatic environment will be limited based on its reported use pattern.

7.2. Environmental Effects Assessment

No ecotoxicological data was submitted. The notified polymer has NAMW > 1,000 Da and contains no significant ionic functionality; however it contains a pendant methacrylate group with FGEW < 5,000.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) has not been calculated since no ecotoxicological data are available.

7.3. Environmental Risk Assessment

A Risk Quotient (PEC/PNEC) has not been calculated as release of the notified polymer to the aquatic environment will be limited, based on its reported use pattern. Therefore, based on the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

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