File No PLC/1003

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

POLYMER OF LOW CONCERN PUBLIC REPORT

Dispersant SK 001

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Australian Government Department of Sustainability, Environment, Water, Population and Communities.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This Public Report is also 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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

December 2011

Table of Contents

SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
PLC/1003	3M Australia Pty Ltd and International Sales & Marketing	Dispersant SK 001	No	≤20 tonnes per annum	Component of printing inks and coatings

CONCLUSIONS AND REGULATORY OBLIGATIONS

Human Health Risk Assessment
Based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the health of workers and the public.

Environmental Risk Assessment
Based on the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Health and Safety Recommendations

- Employers should implement the following safe work and engineering practices to minimise occupational exposure to the notified polymer during reformulation and spray application:
  - Avoid contact with skin and eyes

- Service personnel should wear cotton or disposable gloves and ensure adequate ventilation is present when replacing ink containers containing the notified polymer and during routine maintenance and repairs.

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

- Spray application should be carried out in accordance with the Safe Work Australia *National Guidance Material for Spray Painting* [NOHSC (1999)].

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

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

Disposal
- The notified polymer should be disposed of to landfill.

Emergency Procedures
- Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.

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

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 polymer 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 polymer, 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 notified polymer is introduced in a chemical form that does not meet the PLC criteria.

or

(2) Under Section 64(2) of the Act; if
- the function or use of the notified polymer has changed from a component of printing inks and coatings, or is likely to change significantly;
- the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
- the notified polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the notified 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 MSDS of the notified polymer and products containing the notified polymer were provided by the applicants. The accuracy of the information on the MSDS remains the responsibility of the applicants.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

Applicants
3M Australia Pty Ltd (ABN 90 000 100 096)
Building A, 1 Rivett Road
North Ryde NSW 2113

International Sales and Marketing (ABN 36 467 259 314)
260-262 Highett Road
Highett VIC 3190

Exempt Information (Section 75 of the Act)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, polymer constituents, residual monomers/impurities and use details.

2. IDENTITY OF POLYMER

Marketing Name(s)
Dispersant SK 001 (neat notified polymer)
Component of Piezo Ink (contains up to 10% notified polymer)
Component of Scotchkote coatings (contains up to 10% notified polymer)

Molecular Weight
Number Average Molecular Weight (Mn) is > 1,000 Da.

Reactive Functional Groups
The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

Criterion	*Criterion met*
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
Low Charge Density	Yes
Approved Elements Only	Yes
Stable Under Normal Conditions of Use	Yes
Not Water Absorbing	Yes
Not a Hazard Substance or Dangerous Good	Yes

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa	Yellowish liquid
Melting Point/Glass Transition Temp	Approx. 17°C
Density	1050 kg/m^3 at 25°C
Water Solubility	> 200 g/L at 20°C*
Dissociation Constant	Not determined
Particle Size	Not relevant
Reactivity	Stable under normal environmental conditions
Degradation Products	Not known

*A mixture of 1 part notified polymer in 4 parts water was soluble, indicating that the water solubility was >200 g/L.

5. INTRODUCTION AND USE INFORMATION

Maximum Introduction Volume of Notified Chemical (100%) Over Next 5 Years

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	5	10	10	15	20

Use
Component of printing inks and coatings.

The notified polymer will be imported neat (~10% of import volume), or as a component of finished ink products or anticorrosion metal coatings (~90% of import volume) at up to 10% concentration. The neat notified polymer will be reformulated into water-borne flexographic ink products as well as water-based metal primer coatings containing the notified polymer at up to 10%.

6. HUMAN HEALTH RISK ASSESSMENT

The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. This is supported by tests submitted on the following toxicological endpoints.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline*
Rat, acute oral	LD50 >5000 mg/kg bw	no	FHSA* Protocol No. 001/P203
Rabbit, skin irritation	slightly irritating	yes	FHSA* Protocol No. 002/P201
Rabbit, eye irritation	slightly irritating	yes	FHSA* Protocol No. 003/P202

* Federal Hazardous Substances Control Act

All results were indicative of low hazard.

Acute oral toxicity
Ten Wistar derived rats (5 M/5 F) were given a single dose of 5000 mg/kg of neat notified polymer by oral gavage. Two out of ten rats died on the day of administration. The only clinical signs prior to death in these animals was a discharge of the test material from the mouth. Discolouration of the lungs (red) and intestine (red & brown) were observed upon necropsy. It is quite likely that these animals died from a dosing accident. Most of the surviving animals also exhibited mouth and nasal discharge on days 0 and 1. All rats recovered to an active and healthy condition by day 2 and gained weight over the study period.

Skin irritation
The skin irritation potential of the neat notified polymer was tested in six New Zealand White rabbits. The test material was applied under occluded dressing to the shaved skin (abraded and intact sites) for 24 hours and observation was made at 24 and 72 hours.

At 24 hours after removal of the dressing, well defined to moderate erythema was observed at the abraded and intact sites of all animals. Slight oedema was observed for five rabbits. In addition, eschar was observed at two abraded sites. Erythema and eschar formation score was 2.33 and 2.00 for abraded and intact skin, respectively. Oedema formation score was 1.50 and 1.0 for abraded and intact skin, respectively.

At 72 hours, the erythema had decreased or remained stable in 5 of 6 animals, with eschar or blanching still noted at the same two abraded sites. The remaining rabbit had severe erythema and thickening of the skin at one abraded sites, while the intact site still had well-defined erythema. Oedema cleared in one rabbit, was evident as very slight in one previously unaffected rabbit and remained stable or decreased slightly in the other four animals. Erythema and eschar formation score was 1.83 and 1.50 for abraded and intact skin, respectively. Oedema formation score was 1.00 and 0.67 for abraded and intact skin, respectively.

Based on the above scores, the notified polymer is irritating to abraded skin and moderately irritating to intact skin. However, it is noted that the test substance was applied for 24 hours instead of the standard 4 hours as stipulated in the OECD test guideline for skin irritation (TG404), hence the skin irritation effects of the notified polymer observed above may not be a true representation of its effects. In this regard, it is also noted that only slight eye irritation was noted in the eye irritation study described below. Based on the results of the skin irritation study on intact skin and taking in account of the long exposure time and the results of the eye irritation study and the absence of structural alerts, NICNAS concludes that the notified polymer cannot be classified as a skin irritant under the Approved Criteria but may present as a slight skin irritant.

Eye irritation
The eye irritation potential of the neat notified polymer was tested in six New Zealand White rabbits. At 24 hours after dosing, all treated eyes exhibited slight conjunctival irritation manifested as

hyperaemia and/or chemosis. Five of the six eyes were free of all irritation by 48 hours and the remaining eyes by 72 hours. No corneal opacity or iridial damage was observed in any treated eye during the test period. Aside from the observed eye irritation, all animals appeared active and healthy during the test period.

Occupational Health and Safety Risk Assessment
The notified polymer meets the PLC criteria and is therefore assumed to be of low health hazard. However, based on toxicological studies provided by the notifier, the notified polymer may present as a slight skin or eye irritant.

Given the concentration in end use products is ≤ 10%, workers most at risk of slight irritation effects will be workers handling the neat notified polymer. These workers are expected to wear PPE that should minimise exposure and hence the risk.

The finished coatings will be applied by spray application, hence there is also potential for inhalation exposure, although this is expected to be low given the low concentration (≤ 10%) of the notified polymer in the coatings. In addition, the notifier states that the majority of the spray applications will occur in ventilated spray booths using protective equipment including respiratory protection, further minimising inhalation exposure. Furthermore, the notified polymer is water soluble and has a number average molecular weight < 10,000 Da and is therefore, expected to be readily cleared from the lungs and not cause a lung overloading effect.

Overall, based on the assumed low hazard and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the health of workers. However, given the notified polymer may have the potential for slight skin and eye irritation, workers should take steps to avoid skin and eye contact when handling the neat notified polymer.

Public Health and Safety Risk Assessment
The notified polymer and products containing the notified polymer will not be sold to the general public. However, the public may come into contact with the notified polymer during use of products that have been coated or printed with coatings, paints or inks containing the notified polymer. As the notified polymer will be bound within a matrix after drying and will not be bioavailable, exposure to the general public is expected to be limited. Therefore, the risk to general public from dermal exposure to the notified polymer is not considered to be unreasonable.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. Polymers without significant ionic functionality are generally of low concern to the environment, although some non-ionic polymers with monomers arranged in blocks may cause toxicity to aquatic organisms. However, most of the notified polymer will be incorporated and bound within an inert matrix on plastic and metal substrates when used as a component in ink or in metal primer coating, and is, therefore, not expected to be bioavailable. Release of the notified polymer to the aquatic environment is not expected to be significant at any stage in the lifecycle of the notified polymer within Australia. Residues from reformulation and end-use equipment washings and from storage containers are expected to be collected and, after solidification, be disposed of to landfill. During use as ink, the majority of the release to the environment is from spills (1%) that are contained and disposed of to landfill. Up to 50% of the notified polymer may be released as overspray during use as a metal primer coating. The notified polymer from overspray is collected and disposed of to landfill. Again there is minimal release to the aquatic environment from cleaning of spraying equipments and spray booth scrubber water as most of the notified polymer is removed as cured paint. The notified polymer will share the fate of the articles into which it is incorporated. It is expected to be disposed of to landfill or recycled. The notified polymer is expected to eventually degrade in landfill, or by thermal decomposition during metal reclamation, to form water

and oxides of carbon and silicon. Due to its high molecular weight, the notified polymer will not readily cross biological membranes, and a low potential for bioaccumulation is predicted.

Therefore, based on its reported use pattern in industrial settings, the notified polymer is not considered to pose an unreasonable risk to the environment.