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NATIONAL INDUSTRIAL C HEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

POLYMER IN HYPERMER CG6

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Acting Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

POLYMER IN HYPERMER CG6

1. APPLICANT

ICI Australia (Operations) Pty Ltd of 1 Nicholson Street MELBOURNE VICTORIA 3000 has submitted a limited notification statement for an assessment certificate for Polymer in Hypermer CG6 ..

2. IDENTITY OF THE CHEMICAL

Polymer in Hypermer CG6 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formula, molecular weight, spectral data and details of the polymer composition have been exempted from publication in the Full Public Report and the Summary Report.

Trade Names: Hypermer CG6 (32% active)

Method of Detection and Determination: the following analytical spectra were provided: infrared spectroscopy (IR) used for identification; ^{1}H-NMR (nuclear magnetic resonance) and ^{13}C-NMR spectra were provided to determine structure; gel permeation chromatography (GPC) used to determine molecular weight and weight distribution

3. PHYSICAL AND CHEMICAL PROPERTIES

The following data refer to the product containing 32% of the notified polymer.

Appearance at 20°C and 101.3 kPa: red brown translucent liquid

Boiling Point: 100°C (at 760 mm Hg)

Specific Gravity: 1.08 at 25°C

Vapour Pressure: not determined but expected to be negligible due to its high molecular weight

Water solubility: not determined but expected to be very soluble as

	it has a similar hydrophile lipohile balance (HLB) number to other highly water soluble surfactants and contains a high proportion of polyethylene glycol which is water soluble
Partition Co-efficient (n-octanol/water):	not determined as the polymer is not expected to cross biological membranes but K_{ow} is expected to be low
Hydrolysis as a Function of pH:	not determined, the polymer contains hydrolysable ester groups but this is not likely at the environmetal range of pH 4-9
Adsorption/desorption:	not determined but expected to be low due to high water solubility
Dissociation Constant:	not determined as "the polymer is non-ionic and will not dissociate in water"; it is however noted that a low percentage of free COOH which are expected to have typical acidity
Flash Point:	76.5°C
Flammability Limits:	upper explosive limit = 12.6% lower explosive limit = 2.6%
Autoignition Temperature:	420°C
Explosive Properties:	stable and not expected to deteriorate as a result of exposure to heat, friction or shock
Reactivity/Stability:	stable under conditions of use but should avoid contact with strong oxidising agents

4. PURITY OF THE CHEMICAL

Degree of Purity: > 99%

5. USE, VOLUME AND FORMULATION

The notified polymer will not be manufactured in Australia but imported at an estimated quantity of 320 - 3 200 kg in the first year and 3 200 - 32 000 kg per annum in the next four years. Initially the notified polymer will be used as a surfactant in a seed dressing formulation, and subsequently may be used in different pesticide formulations.

Polymer in Hypermer CG6 has been used in Europe since 1990 as an agricultural chemical formulation additive and as a pigment dispersant in the ink industry.

6. OCCUPATIONAL EXPOSURE

Polymer in Hypermer CG6 will be imported via seafreight in 200 litre drums and stored at a single site and and transported by road to agricultural chemical formulation sites. As the polymer is in closed containers, potential exposure would only be through accidental spills in the event of an accident during transport, loading or unloading.

Two groups of workers will be exposed to the notified polymer those:

- manufacturing agricultural chemical formulations; and
- using the agricultural chemical formulations.

At pesticide reformulation sites, the polymer solution will be manually transferred from 200 litre drums into feeding tanks and fed into enclosed mixer tanks with other ingredients. Typically the process is carried out under local exhaust ventilation for extraction of escaped vapour and dust. Mixer washouts between batches and any spillage into sumps and bunds are recycled into a holding tank for use in the subsequent batch. Drums of Hypermer CG6 are similarly washout and washings combined in the holding tank.

Transfer of the final product and filling operations will be conducted under local exhaust ventilation. Filling is semi-automatic in nature with operators required to load bottles to the filling line and seal with bungs. The notified polymer is present at a rate of 1 - 5% by weight in the formulated product.

At the end users' sites, pesticide is applied to seed at a rate of one litre per tonne of seed and the seed is sown at a rate of 50 kg per hectare and wheat is harvested at a typical yield of 2.5 tonnes per hectare. At a typical surfactant concentration of 2%, concentration of notified polymer is 6.4 g per tonne of seed or 0.32 g sown hectare or 128 mg per tonne of harvest wheat.

There is potential for inhalational and dermal expsure during both formulation and application of products containing the notified polymer.

7. PUBLIC EXPOSURE

The notifier has not specified the types of agricultural chemical formulations in which the product containing the polymer may be used, and it appears that it may be used in a wide range of pesticide formulations (eg insecticides, herbicides, fungicides). Its used in a fungicide/insecticide co-formulation used to protect wheat form spoilage during storage and planting is cited as a typical application. It is noted that the introduction of new agricultural formulations, including those containing Hypermer CG6, is controlled by the National Registration Authority for Agricultural and Veterinary Chemicals.

The notifier has indicated that due to the hazardous nature and cost of agricultural actives, all possible steps are taken to minimise wastage. In production of agricultural products, mixer washouts and any spillages are recycled into holding tanks for use in the next batch preparation. Contaminated washout or spills, unable to be recycled, are sent to the Brisbane City Council Hazardous Waste Treatment Plant for neutralisation and soldification with concrete and fly ash, prior to burial. It is estimated that up to 100 kg Hypermer CG6 per annum (equivalent to 32 kg of the notified polymer) may be disposed of by this method. On farms, empty containers are rinsed and the rinsate added to the mixer prepared for use. Empty containers may be crushed or punctured and buried in local landfill.

It is difficult to estimate the degree of public exposure to the notified polymer in the absence of information on the range and type of agricultural products in which it is to be used. The potential for exposure may be significant if Hypermer CG6 is used in agricultural formulations intended for use in food producing crops, or in formulations marketed for home garden use. The water solubility of the polymer suggest that it would have the potential to enter aquatic environments, and no information was provided on its environmetal chemistry or fate in water. However, it is noted that the concentrations of surfactants used in agricultural formulations, shch as those containing the notified polymer from the requirement of a tolerance for residues when used as inert ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest, on the basis of low concern for toxicity based on the polymeric nature of the chemical.

8. ENVIRONMENTAL EXPOSURE

Release

Initially the notified polymer will be used by Rhône-Poulenc Rural Australia in Queensland. As the product will be transported in closed containers, potential release would only be through accidental spills. The Material Safety Data Sheet (MSDS) contains adequate procedures to protect the environment.

In the manufacture of agricultural chemical formulations, the product will be simply mixed with other ingredients, occasionally under high shear conditions, and placed into containers for distribution to resellers. No elevated temperatures or pressures are involved. Any spills and the rinses from mixers are recycled into holding tanks for use in the next manufacturing batch. Spills or washings not held for reuse (e.g. contaminated with lubricating oils or other pesticides) will be sent to the Brisbane City Council Hazardous Waste Treatment Plant at Willawong for disposal (estimated 100 kg of Hypermer CG6 per year will be disposed of in this fashion). Empty drums that have been washed out are sent to a drum recycler.

In the application of pesticides, standard practice is to triple or pressure rinse containers and add the rinsate to the seed dressing mixture. Empty containers are crushed, punctured and buried at landfills or disposed of according to local regulations.

By far the largest and most widespread release of the polymer to the environment will be in the use of pesticides containing it. Hypermer CG6 may be used in a range of pesticides which may have different application rates and use patterns. A typical pesticide would be a seed dressing containing a fungicide and an insecticide. For this use pattern, the pesticide is applied to seeds, thoroughly mixed, and then the seeds sown in the field or stored for planting later. ICI Australia estimated a typical environmental concentration of 1 g of notified polymer per hectare of sown seed based on a pesticide application rate of 1L/1,000 kg/seed, 2% Hypermer CG6 in the pesticide and a wheat sowing rate of 50 kg seed/ha. However, based on data provided by ICI Australia and Rhône-Poulenc Rural Australia Pty Ltd, worst-case estimated environmental concentrations (EEC) were calculated as follows:

The end-use product (EUP) Real Professional Seed Dressing Fungicide contains 30 g of Hypermer CG6 (Atlox 4913) per litre. Since Hypermer CG6 is 32% notified polymer, the fungicide will contain 30 g Hypermer CG6/L X 0.32 = 9.6 g polymer/L.

The maximum proposed application rate of this fungicide based on the draft label is 150 mL EUP per 100 kg/seed (wheat, barley or oats). Thus the application rate of polymer will be 150 mL EUP·100 kg/seed X 9.6 g polymer/L = 14.4 mg polymer·kg/seed^{-1}.

Wheat, barley and oats are typically sown at rates of 60 - 80, 50 - 70 and 40 - 50 kg seed/ha, respectively, in Victoria (2) which are representative of the higher rates sown in Australia. In a worst case scenario using the maximum rate of 80 kg seed·ha^{-1}, the application rate of polymer in sown fields will be 80 kg seed/ha X 14.4 mg polymer·kg/seed = 1.15 g polymer/ha.

If these grain crops are sown at a depth of 1 cm, then the volume of soil over 1 ha would be 100 m X 100 m X 1 cm = 100 m^3. Presuming a soil density of 1,300 kg/m, the mass of this volume of soil would be 100 m^3 X 1,300 kg/m^3 = 130 000 kg. The EEC of polymer in 1 ha of soil would be 1.15 g polymer ÷ 130 000 kg = 8.8 µg polymer/kg/soil.

If the sown field were then subject to 20 mm of rain, the volume of water over each ha of field would be 100 m X 100 m X 20 mm = 200,000 L. If this entire volume were surface runoff and the all polymer were mobilised, the EEC in surface runoff would be 1.15 g polymer/ha ÷ 200,000 L/ha = 5.75 µg/L.

As it is unknown if the notified polymer will be used in future pesticide formulations, the EEC calculation cannot account for these possible additional use patterns and subsequent releases to the environment.

Fate

The company submitted a study on the biodegradability of Hypermer CG6 conducted according to a modified UK Department of the Environment method and OECD Test Guideline 301F. The biodegradability was determined to be 38% after 28 d at 20±2°C when expressed as a ratio of the biochemical oxygen demand (BOD) to the chemical oxygen demand (COD). On the basis of total organic carbon removal, Hypermer CG6 was 55% biodegraded after 28 d. No information was given

on the biodegradation of the notified polymer itself which makes up only 32% of the product. It is expected that a large proportion of the biodegradation that occurred during the test was that of propylene glycol, a solvent making up 36% of the final product, and polyethylene glycol, which is an expected product in the first hydrolysis step of the polymer.

The probable degradation pathway of the notified polymer provided by ICI Australia begins with the fission of the methoxypolyethyleneglycol chains from the polymethacrylic backbone by hydrolysis of the ester linkage. All surface activity is lost after this step. Next, methyl oxidation at either end of the polyethyleneglycol chain forms carboxyl functional groups which can then be beta oxidised ultimately to water and carbon dioxide. The polymethacrylic backbone is expected to precipitate as the Ca or Mg salt and then slowly biodegrade by methyl and beta oxidation.

9. EVALUATION OF TOXICOLOGICAL DATA

The Act does not require the provision of toxicological data for polymers with number-average molecular weight (NAMW) > 1000. However, the following studies on acute oral toxicity, eye irritation and skin sensitisation were provided for Hypermer CG6

9.1 Acute Toxicity

Summary of the acute toxicity of

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 2000 mg/kg	(3)
eye irritation	rabbit	slight irritant	(5)
skin sensitisation	guinea pig	non-sensitiser	(6)

9.1.1 Oral Toxicity (3)

Species/strain:	Sprague Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	given orally by gavage
Clinical observations:	no abnormalities were observed
Mortality:	no deaths
Morphological findings:	no abnormalities were noted at necropsy
Test method:	based on OECD Guidelines for Testing of

	Chemicals (4)
LD_{50}:	> 2000 mg/kg
Result:	low oral toxicity in the rat

9.1.2 Eye Irritation (5)

Species/strain:	New Zealand White Rabbits
Number/sex of animals:	3 males
Observation period:	three days at 24 hour intervals
Method of administration:	notified polymer as 32% active
Irrigated eyes:	slight conjunctival redness and slight to moderate discharge one hour after dosing; no additinal signs of irritation observed
Test method:	based on OECD Guidelines for Testing of Chemicals (4)
Result:	slight irritant to the rabbit eye

9.1.6 Skin Sensitisation (6)

Species/strain:	Perbright Albino guinea pigs (males)
Number of animals:	20 test; 10 control
Induction procedure:	three pairs of injections of 0.1 ml: Hypermer CG6; FCA in distilled water (1:1) topical induction: at day 6, 100% Hypermer CG6 for 48 hours
Challenge procedure:	a challenge was conducted two weeks after induction using 30% (top left)and 100% (top right) Hypermer CG6 for 48 hours

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hrs****	***48 hrs****	***24 hrs***	***48 hrs***
30%	**0/20	0/20	0/10	0/10
100%	0/20	0/20	0/10	0/10

* time after patch removal
** number of animals exhibiting positive response

Test method:	based on OECD Guidelines for Testing of Chemicals (4)
Result:	non-sensitiser to guinea pig skin

9.2 Overall Assessment of Toxicological Data

Based on studies done and information provided by the notifier, the notified polymer may be of low acute oral toxicity in rat, slight irritant to the eye of rabbit and non-sensitiser to guinea pig skin.

On the basis of submitted data, the notified polymer will not be classified as hazardous in accordance with *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(1994)] in relation to acute orat toxicity, eye irritation and skin sensitisation.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The company submitted a study on the toxicity of Hypermer CG6 to *Daphnia magna* following OECD and EEC guidelines. The calculation of the EC_{50} was based on a method not considered valid and was recalculated by the EPA using probit analysis to yield 373 (306, 457) mg Hypermer CG6/L. As the notified polymer makes up only 32% of Hypermer CG6, the 48-h EC_{50} of the polymer is approximately 120 (98, 146) mg a.i./L based on nominal concentrations and assuming there were no confounding effects from other components of the formulation.

The company stated that their experience has been that daphnids are more sensitive in acute toxicity tests than both fish and algae for surfactant type chemistry and that additional testing on these organisms are considered unnecessary. However, no studies were provided to support this claim.

No other ecotoxicology studies were provided which is acceptable for polymers with a NAMW > 1000 according to the *Act*. However, summary data on two expected degradation products, polyethylene glycol and polyacrylic acid, were submitted. Polyethylene glycol had a 24-h LC_{50} to goldfish of > 5,000 mg a.i./L and a 15-min EC_{50} to *Photobacterium phosphoreum* of > 100 mg a.i./L. Polyacrylic acid was practically non-toxic to zebra fish (LC50 > 200 mg a.i./L), bluegill sunfish (LC_{50} > 1,000 mg a.i./L), *D. magna* (LC_{50} > 200 mg a.i./L) and the alga *Scenedesmus subspicatus* (EC10 = 180 mg a.i./L) in 48 and 96-h experiments (7). In 21-d daphnid reproduction tests, however, divergent results were obtained with NOEC values of 12 and 450 mg a.i./L in different experiments. It also had a low toxicity to earthworms (LC_{50} > 1,000 mg a.i.·kg/soil) and did not inhibit the growth of corn, soybean, wheat and grass seeds at up to 225 mg a.i.kg/ soil. Nabholz et al. () report that polyacrylic acid is moderately toxic to green algae.

For surfactants with MW > 1,000, toxicity is generally low when the hydrophobic component is small relative to the hydrophilic component (8). For the notified polymer, this is expected to be true given its high water solubility.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The most likely and widespread environmental exposure of the notified polymer will result from its intended use as a surfactant in pesticide manufacture and subsequent distribution in agricultural areas as a seed dressing. One study was submitted on the biodegradation of the product Hypermer CG6, containing the notified polymer at 32%, which showed some biodegradation after 28 d. No other studies were submitted on the transformation of the polymer by photodegradation, hydrolysis or other pathways. No studies were submitted on the toxicity of the polymer to soil organisms which will likely have the greatest exposure. As well, the hazard to birds is unknown if seeds coated with the polymer are ingested (if not sown properly or spilled and not cleaned up) as no avian toxicity data were presented.

ICI Australia argues that although the expected release of polymer to the environment may seem high, the EEC in soil (1 g polymer/ha, 0.02 mg/kg soil) will be low and therefore the risk to terrestrial organisms will be similarly low. While the EPA concurs with the magnitude of these values, other possible pesticide formulations, use patterns and application rates may increase the EEC. As well, the company argues that “Hypermer CG6 is unlikely to be harmful to birds as the potential exposure is about two orders of magnitude below the level at which toxicity is observed in the most sensitive [aquatic] species” in testing with polyethylene glycol and polyacrylic acid. This reasoning is flawed as there exist large degrees of uncertainty in the extrapolation of sensitivities from aquatic organisms to birds, and between the toxicities of the degradation products to the parent polymer. Regardless of what the EEC may be, in the absence of toxicity data to terrestrial organisms, it is not possible to fully evaluate the hazard in this environment.

After the polymer has entered the soil environment, the expected high water solubility indicates a potential to leach to groundwater or runoff to surface water. This potential cannot be assessed, however, as no studies were submitted regarding the mobility of the polymer in soil. As well, no information was provided on its environmental chemistry and fate in water. A study with *D. magna* showed the polymer was practically non-toxic with an EC_{50} of approximately 120 (98, 146) mg a.i./L. ICI Australia calculated an EEC in surface runoff water of 5 µg/L (EPA worst case EEC = 5.75 µg/L) which is significantly lower than the concentration causing adverse effects and thus the hazard to daphnids in the proposed seed dressing use is expected to be acceptably low. Although the toxicity to other aquatic organisms is unknown, the hazard from this use is expected to be similarly low given the low EEC.

If the proposed use of the polymer is restricted to the seed dressing only, the low application rate of 1.15 g polymer/ha is expected to reduce the hazard to a low level. In the event that other pesticide formulations will contain the polymer, the increased environmental exposure and EEC together with the unknown biodegradation and transformation potential may lead to unacceptable persistence in the environment

and potential hazard to terrestrial and aquatic organisms; a secondary notification and additional data will then be required.

The environmental hazard from spills and accidental releases is not expected to be high as these occurrences are unlikely and measures are in place to ensure containment and clean up.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

No data on effects of humans were available for assessment. However, based on results of animal studies done on Hypermer CG6 (32% of notified polymer), the notified polymer is likely to exibit low acute oral toxicity and slight eye irritation and unlikely to present a risk of skin sensitisation to workers. In addiition, adverse systemic effects (from dermal absorption) are unlikely due to the high NAMW of the notified polymer. The level of residual monomers in the notified polymer are

unlikely to present a health hazard. There are no hazardous impurities present in sufficient concentrations to render the polymer hazardous.

As the polymer is available in liquid form, skin and eye contact will be the main source of occupational exposure during persticide formulation. Inhalational exposure during these activities is unlikely as the polymer vapour pressure is expected to be low and no loss to the working environment will occur as a result of the specific dosing system. The use of local exhaust ventilation would further minimise worker exposure during manual tranfer operations.

The risk of adverse occupational health effects by the end user is expected to be low, due to low exposure levels and the high molecular weight of the notified polymer. However, during pesticide formulation and use precautions against continued exposure to other ingredients should be observed.

It is difficult to estimate the degree of public exposure to the notified polymer in the absence of information on the range and type of agricultural chemical formulations in which it is to be used. This has not been specified by the notifier, although it appears that it may be used in a wide range of such formulations. The potential for exposure may be significant if Hypermer CG6 is used in agricultural formulations intended for use in food producing crops, or in formulations marketed for home garden use. However, it is noted that the concentrations of surfactants used in agricultural formulations, such as those containing the notified polymer, are typically low. Additionally, it is noted that the US EPA in 1994 exempted the notified polymer from the requirement of a tolerance for residues when used as inert ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest, on the basis of low concern for toxicity based on the polymeric nature of the chemical.

Further, any new agricultural product which contains the notified polymer as a non-constituent, would be required to be registered to be registered by the National Registration Authority for Agricultural and Veterinary Chemicals. Part of the

registration process involves a detailed consideration of the risk to public health posed by new products, which may involves consideration of the toxicological profile of the new product. Where appropriate, controls may be imposed by poisons scheduling in the Standard for Uniform Scheduling of Drugs and Poisons of appropriate first aid and safety directions for the label.

Based on the provided information and the intended usage, the polymer in Hypermer CG6 does not appear to represent a significant hazard to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to polymer in Hypermer CG6 the following guidelines and precautions should be observed:

- If engineering controls are not sufficient to control exposure to the notified polymer the following protective equipment should be worn:

  Chemical-type goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (9) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (10);

- Safe practices, as should be followed when hanndling any chemical formulation, should be adhered to - these include:

  Minimising spills and splashes,

  Practising good personal hygiene,

  Practising good housekeeping and maintenance including bunding of large spills which should be cleaned up promptly with absorbents and put into containers for disposal;

- It is expected that, in the industrial environment, protective clothing conforming to and used in accordance with AS 2919 (11) and protective footwear conforming to AS/NZS 2210 (12) should be worn as a matter of course; in addition it is advisable when handling chemical formulations containing the notified polymer to wear respiratory protection conforming to AS/NZS 1715 (13) and AS/NZS 1716 (14) and impermeable gloves conforming to AS 2161 (15) to protect against unforseen circumstances;

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

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical in Hypermer CG6 was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (16).

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

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