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28 September 2007

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

FULL PUBLIC REPORT

HELICONE® HC

This Self Assessment has been compiled by the applicant and adopted by NICNAS in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS), administered by the Department of Health and Ageing and the Department of the Environment and Water Resources has screened this assessment report. The data supporting this assessment will be subject to audit by NICNAS.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full 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:

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**Director
NICNAS**

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FULL PUBLIC REPORT**HELICONE® HC****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT

WACKER CHEMIE AG (ABN 11 607 113 062)

C/- 18/20 Duerdin Street

Clayton North; VIC 3168

NOTIFICATION CATEGORY

Self Assessment: Polymer of Low Concern

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 and Residual Monomers/Impurities.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

Advice on introduction of a new chemical for non-cosmetic use at less than 10 kg per 12-month period (2003).

NOTIFICATION IN OTHER COUNTRIES

Canada: listed on DSL

China: listed on IECSC

EU: listed on ELINCS (ELINCS no. 431-820-0)

Japan: Polymer Flow Scheme submitted and approved on April 22, 2004

Korea: Government Gazette listing No 2000-3-1526

USA: PMN-NR. P-00-30, NOC 31.03.00; confidential, Generic Name: modified polyacrylate

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

HELICONE® HC

HELICONE® HC SAPPHIRE; JADE; SCARABEUS; MAPLE

HELICONE® HC S SAPPHIRE; JADE; SCARABEUS; MAPLE

HELICONE® HC XL SAPPHIRE; JADE; SCARABEUS; MAPLE

MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (NAMW) > 10,000

REACTIVE FUNCTIONAL GROUPS

The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met</i>
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	Colourless – yellowish-white powder
Melting Point/Glass Transition Temp	Not available; decomposition temperature 350 °C, decomposition starts at 300 °C
Density	1290 kg/m ³ at 20 °C (solid)
Water Solubility	Virtually insoluble, < 50 mg/L at 20°C Tested according to EC test guideline A.20 at 3 different pH values.
Particle Size	Platelets of approx. 15 – 35 µm size (D50) and 5 µm thickness; platelets of approx. 300 µm size (D50) and 5 µm thickness for the XL products
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

5. INTRODUCTION AND USE INFORMATION

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>	1	1	1	1	1

USE AND MODE OF INTRODUCTION AND DISPOSAL

Mode of Introduction

The product is supplied in 40 g PE bottles, 400 g PE bottles, 1 kg plastic bag inside a metal can, 10 kg metal cans. Transport is via air, rail or road.

The notified polymer will be imported in its pure form or in formulated products.

Reformulation/manufacture processes

Customers receiving the product will usually

- mix it with liquid formulations (paint, ink) by stirring in a vessel
- dryblend it with resins etc. to formulate a powder coating
- dryblend it with plastic pellets before extruding a polymer compound

Use

HELICONE® HC creates special decorative effects. The polymer is formulated with coatings, inks or plastics primarily to enhance the surface appearance of automobiles and consumer goods. Approximately 70% is used in the field of coatings, 30% in plastics.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

OCCUPATIONAL EXPOSURE

When the notified polymer is imported in a formulated product (e.g. a liquid coating formulation) no occupational exposure to particles of the notified polymer would be expected.

The notified polymer will also be imported in its pure form into Australia for formulation of liquid or dry coatings or for blending it with plastic pellets. For liquid coatings, it will be mixed in a low shear mixer with liquid binders (water based), additives and fillers to create the final product (coating). Similarly, the notified polymer would be added to a mixer with the remaining ingredients for a dry coatings product. Or the notified polymer will be blended with plastic pellets and possibly other additives for plastics. The mixer will be cleaned out with water or solvents. Very little if any of the polymer is expected to be released to the workplace environment due to process conditions.

Worker exposure to dust of the notified polymer would be expected when adding the notified polymer (likely to be a manual operation) to the mixer. The mixing process for liquid or dry coatings formulations or for plastics could create some dust, which should be removed with an air hood with filter. In case of dust formation during manual operations workers are advised to use an appropriate fine dust mask.

During use of the formulated dry coating, spray application of the liquid coating or extrusion of a polymer compound, control of occupational exposure would be through the control of dust and aerosol formed during these processes either by air hoods with filter or with fine dust masks where there is human interaction required.

PUBLIC EXPOSURE

Direct public exposure is not to be expected for this industrial chemical. The notified polymer will be used mainly in industrial processes and the public will only be exposed to the final article coated or pigmented with the notified polymer. The notified polymer is then bound inextricably in the matrix of the final article (if used as pigment in plastics) or in the matrix of the coating. Therefore there is no public exposure to the notified polymer.

6.2. Toxicological Hazard Characterisation

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by toxicological endpoints observed in testing conducted on the notified polymer (Genotoxicity) or an analogue polymer (Helicone HCP, was used for the acute oral, skin irritation, eye irritation and skin sensitisation tests).

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>	<i>Test Guideline</i>
Rat, acute oral	LD ₅₀ > 2,000 mg/kg bw *	no	no	limit test, no signs of toxicity
Rabbit, skin irritation	non-irritating *	no	no	OECD TG 404
Rabbit, eye irritation	non-irritating *	no	no	OECD TG 405
Skin sensitisation - adjuvant test	no evidence of sensitisation *	no	no	OECD TG 406 (Buehler and Maximisation tests)
Genotoxicity - bacterial reverse mutation	non mutagenic	no	no	OECD TG 471

* Results taken from tests with HELICONE® HCP, which is chemically and physically very similar to HELICONE® HC.

Taking into account the physical-chemical properties of the new polymer together with toxicological data, the following assessment can be made:

The notified polymer is non-toxic by ingestion and after dermal application. There is no indication of relevant skin and eye irritation and skin sensitization. Mutagenic (genotoxic) activity of the new polymer was not observed. According to available data the new polymer is classified as a non-hazardous substance.

6.3. Human Health Risk Assessment

OCCUPATIONAL HEALTH AND SAFETY

Although exposure to the notified polymer could occur during manual handling (addition to mixing operations), the risk to workers is considered to be low due to the intrinsic low hazard of the notified polymer.

The notified polymer is of high molecular weight, insoluble and non-water absorbing, with an estimated Molecular Weight > 10000 Daltons and estimated by the notifier to be larger than 100000 Daltons. Potential risk from inhalation of this inert polymer is low, based on its particle size of greater 10 microns with an average of 35 microns.

No relevant toxicity has been observed in various in vitro and in vivo tests. Nonetheless, common workplace hygiene and control of dust, where appropriate with dust masks, is advisable.

PUBLIC HEALTH

Members of the public may make dermal contact with products containing the notified polymer. However, the risk to public health will be negligible because the notified polymer is of low hazard, and is bound inextricably within a matrix in the products available to the public.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

ENVIRONMENTAL RELEASE

The notified polymer will either be imported ready for use (in a formulated coating) or in its pure form as a pigment for industrial applications. The main applications are as a pigment in coatings, inks and plastics.

Environmental release would mainly be expected when the pure notified polymer is imported and formulated in Australia. It will be mixed in a low shear mixer with liquid binders (water based), additives and fillers to create the final product (coating). The typical usage would be between 2 – 5% of pigment in the final formulation. The clean out of the mixing vessel would typically occur with water. The residue remaining in the mixing vessel is estimated to be no more than 2% of the final product, clean-out waste water will therefore contain a maximum of 1 kg of the notified polymer, based on the usage and the import volume.

The mixing process could create some dust, which will be removed with an air hood with filter. The filter waste is ultimately incinerated or land filled.

Residues of the notified polymer remaining in the import containers would be expected to be less than 1%. Based on the import volume, this could amount to 10 kg in total. These import containers will be disposed of either through metal recycling companies or the controlled waste system (plastic cans) and be disposed of by incineration or washed and sent to landfill.

The majority of the notified polymer will be bound within the cured coating matrix adhering to the final article, e.g. car body panels. Once the chemical is within a cured coating it is likely to share the fate of the substrate, which might involve recycling or landfill.

ENVIRONMENTAL FATE

The notified polymer is expected to be stable under normal environmental conditions. Due to its low water solubility, the notified polymer in solid wastes is expected to remain bound within the soils and sediments of landfills and eventually degrade through biotic and abiotic processes. If spilt on land, the notified polymer is expected to bind to soil and become immobilised in the soil layer. If spilt to water, it is not expected to dissolve but rather disperse and settle to sediment. It is not expected to be readily biodegradable but due to its high molecular weight, it is not expected to bioaccumulate. Incineration of the notified polymer will result in the formation of water vapour and carbon dioxide.

7.2. Environmental Hazard Characterisation

No ecotoxicological data were submitted. PLCs without significant ionic functionality are of low concern to the aquatic environment.

7.3. Environmental Risk Assessment

Up to 20 kg per annum of waste notified polymer might be generated during coatings manufacturing and use as a result of incidental spills, equipment cleaning (brushes, rollers, spray equipment), and residues in containers. The majority of this waste will be sent to landfill for disposal. In landfill, the notified polymer in solid wastes is expected to be immobile, and eventually will degrade through biotic and abiotic processes, and consequently, should not pose a significant risk to the environment.

Spills of notified polymer to land are expected to bind to soil and should not be mobile or affect groundwater due to very low water solubility. Spills of notified polymer to waters are not expected to dissolve due to the lack of water solubility, and the product is expected to disperse and to settle to sediment.

Most of the notified polymer used in automotive finishes will eventually be incorporated in metal recycling programs or sent to landfill for disposal following its lifecycle. During reclamation, the notified polymer would be destroyed in furnaces and converted to water vapour and carbon dioxide.

If part of the product was used in other applications than coatings (e.g. pigment in plastics), the release scenario would be similar, some loss from residue in the package, some loss through dust formation (controlled by air hoods) and some loss from equipment cleaning. However, the total estimated amount of notified polymer lost to the environment would not change.

Moreover, the notified polymer is a high value raw material, which will be an incentive to generate as little waste as possible.

8. CONCLUSIONS

8.1. Level of Concern for Occupational Health and Safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

8.2. Level of Concern for Public Health

There is Negligible Concern to public health when used in the proposed manner.

8.3. Level of Concern for the Environment

The polymer is not considered to pose a risk to the environment based on its reported use pattern.

9. MATERIAL SAFETY DATA SHEET

9.1. Material Safety Data Sheet

The notifier has provided MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

10. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Avoid dust formation.
- Avoid dust deposits, remove dust regularly.
- Do not breathe dust.
- In case of dust formation: use fine dust mask without protection rating.
- Do not eat, drink or smoke when handling.
- Use rubber gloves, protective goggles and protective clothes when handling.
- A copy of the MSDS should be easily accessible to employees.

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

- 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.

Environment

- Prevent material from introduction into surface water and into soil.

Disposal

- The notified polymer should be disposed of by incineration in a special waste incinerator. Small quantities may be disposed off by incineration in an approved facility.
- Completely discharge containers. Containers may be recycled or re-used.
- Observe local/state/federal regulations.

Storage

- Keep container dry and tightly closed.
- Observe precautionary measures against dust explosion.

Emergency procedures

- Spills/release of the notified polymer should be handled by mechanical collection. Spilled material should be covered and protected against dispersal by wind until taken up.
- Eliminate all sources of ignition.

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 chemical 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 chemical has changed, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 1000 kg, or is likely to increase, significantly;
 - if the chemical has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical 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.

No additional secondary notification conditions are stipulated.