File No: LTD/1723 and LTD/1724 and LTD/1725

April 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

LTD/1723: Polymer 1 in PSS Additive LTD/1724: Polymer 2 in PSS Additive LTD/1725: Polymer 3 in PSS Additive

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.

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:

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Director NICNAS

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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/1723 &	HP Australia Pty	Polymer 1 in PSS	ND*	≤ 10 tonne/s per	Pigment for inks and
LTD/1724 &	Ltd & DIC	Additive & Polymer 2		annum	paints
LTD/1725	Australia	in PSS Additive &			
		Polymer 3 in PSS			
		Additive			

^{*}ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

As no toxicity data were provided, the notified polymers cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Human health risk assessment

Under the conditions of the occupational settings described, the notified polymers are not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymers are not considered to pose an unreasonable risk to public health.

Environmental risk assessment

On the basis of the PEC/PNEC ratio and the reported use pattern, the notified polymers are not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymers in finished products:
 - Enclosed, automated processes during reformulation, where possible.
 - Adequate ventilation during reformulation processes and spray applications of products containing the notified polymer.
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymers in final products:
 - Avoid inhalation of aerosols
- 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 polymers as introduced and in final products:
 - Respiratory protection, if ventilation is inadequate
 - Gloves
 - Goggles

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2013) or relevant State or Territory Code of Practice.
- A copy of the (M)SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymers are classified as hazardous to health in accordance with the *Globally Harmonised System for the 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.

Disposal

• The notified polymers should be disposed of to landfill.

Emergency procedures

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

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 chemicals 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 polymers are 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 polymers have a number-average molecular weight of less than 1,000;

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymers has changed from pigment for inks and paints, or is likely to change significantly;
 - the amount of the polymers being introduced has increased, or is likely to increase, significantly;
 - the polymers have begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymers 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.

(Material) Safety Data Sheet

The (M)SDS of the notified products containing the notified polymers provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

DIC Australia (ABN: 12 000 079 550)

323 Chisholm Road AUBURN NSW 2144

HP Australia Pty Ltd (ABN: 74 004 394 753) 353 Burwood Highway FOREST HILL VIC 3131

NOTIFICATION CATEGORY

Limited: Synthetic polymer with Mn \geq 1,000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, use details, import volume, site of reformulation and identity of recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT) No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S) None

NOTIFICATION IN OTHER COUNTRIES Korea (2012)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

PSS additive (dry pigment containing the notified polymers) SunFast Blue (ink product containing the notified polymers) P926394 (ink product containing the notified polymers)

OTHER NAME(S) (INK PRODUCTS CONTAINING THE NOTIFIED POLYMERS)

Proprietary Additive PSS: S100 CH116A HP DesignJet 788 Cyan Ink CH130A HP Scitex FB240 Cyan Ink CH216A HP Scitex FB250 Cyan Ink CH120A HP DesignJet 788 Cyan Ink CH220A HP Scitex FB250 Light Cyan Ink

MOLECULAR WEIGHT LTD/1723, LTD1724 and LTD/1725 > 1,000 Da

ANALYTICAL DATA LTD/1723, LTD1724 and LTD/1725 Reference NMR, FT-IR, HPLC, GPC, and UV-vis spectra were provided.

3. COMPOSITION

DEGREE OF PURITY For LTD/1723, LTD1724 and LTD/1725 mixture > 70%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Blue solid (the notified polymers are an inseparable mixture)

Property	Value Data Source/Justification	
Melting Point/Freezing Point	> 450 °C	Measured
Boiling Point	Not determined	Melting temperature greater than
		> 450 °C
Density	$1.23 \times 10^3 \text{ kg/m}^3 \text{ at } 20 ^{\circ}\text{C}$	Measured
Vapour Pressure	$1.5 \times 10^{-15} \text{ kPa at } 25 ^{\circ}\text{C}$	Measured
Water Solubility	$1.25 \times 10^{-3} \text{ g/L at } 20 ^{\circ}\text{C}$	Measured
Hydrolysis as a Function of pH	Not determined	Complex mixture
Partition Coefficient (n-octanol/water)	$\log Pow = 3.43-6.47 \text{ at } 20 ^{\circ}\text{C}$	Measured
Adsorption/Desorption	$\log K_{oc} = 3.52-5.09 \text{ at } 20 ^{\circ}\text{C}.$	Estimated using PCKOCWIN v2.00 (US EPA, 2009).
	Not determined for counter ion.	,
Dissociation Constant	Not determined	The counter ion is cationic. Therefore, it is expected to partition to sludge and soil. The notified polymers are salts and are expected to be ionised under environmental conditions.
Particle Size	Inhalable fraction (<100 μm): 1.7%	Measured
Flash Point	Not determined	Substance is a solid
Flammability	Not highly flammable	Measured
Autoignition Temperature	269 °C	Measured
Explosive Properties	Predicted negative	Measured
Oxidising Properties	Predicted negative	Measured

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity

The notified polymers are expected to be stable under normal conditions of use.

Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the notified polymers are not recommended for hazard classification according to the *Globally Harmonised System for the 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 polymers will be imported as either a component of finished ink products (<1% concentration), paint products (<5% concentration) or dry pigment (at up to 20% concentration) for reformulation into inks or paints.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS For LTD/1723, LTD1724 and LTD/1725 mixture:

Year	1	2	3	4	5
Tonnes	< 1	< 2	< 2.5	< 5	< 10

PORT OF ENTRY Melbourne

TRANSPORTATION AND PACKAGING

When transported as dry pigments (at $\leq 20\%$ concentration) or as ink or paint components (at $\leq 5\%$ concentration), the notified polymers will be packaged in plastic containers/bags in cardboard boxes.

USE

The notified polymers will be used as components (< 5% by weight) of ink and paint products. When used only for digital ink printing in industrial settings, the notified polymers will be imported as components of the finished inks at < 1% concentration.

OPERATION DESCRIPTION

Reformulation

Customers of the notifier will reformulate the dry pigment (containing up to 20% concentration notified polymers) into inks and paints which will then be repackaged for supply for industrial use only. It is expected that this will mainly be via automated processes with controlled batch sizes to limit potential exposure.

End-use

When used as an ink the final product will be contained within ink cartridges for use in industrial inkjet printers. The ink will be printed and UV cured into an inert matrix via automated processes within large format inkjet printers. During the printing process, the ink containing the notified polymers will be transferred directly from the cartridges to the printing heads via automated lines.

Residual ink containing the notified polymers within printing equipment will be removed using cleaning cloths and solvents. Waste materials containing the notified polymers will be disposed through licensed waste disposal contractors..

When used for automotive paints the final products are expected to be applied to vehicles predominantly via spray application. The ink will be cured into an inert matrix on the substrate.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	Exposure Duration	Exposure Frequency (days/year)	
Printer operators	5 minutes/day	Occasional	
Service and maintenance engineers	5-10 minutes/day	Occasional	
Paint application	4 hours/day	200	
Factory workers (reformulation)	8	250	

EXPOSURE DETAILS

Transport and storage

Transport and storage workers are expected to only be exposed to the notified polymers in the unlikely event of an accident. In this case, dermal and ocular exposure may occur; however, standard clean-up procedures would be in place to minimise worker exposure to the notified polymers.

Reformulation

Reformulation workers are expected to come into dermal and ocular contact with the notified polymers at up to 20% concentration. Inhalation exposure is also possible at the reformulation stage. Once the polymer is added to mixing tanks minimal exposure is anticipated due to engineering controls and largely enclosed systems. Following the reformulation processes the notified polymer will be in a liquid formulation and inhalation exposure is no longer anticipated.

End-use – printing

When used as an ink workers may be exposed to the notified polymers at < 5% concentration. The most likely route of exposure is dermal, although inhalation exposure may occur if aerosols are generated. The printing inks containing the notified polymers are contained within a sealed cartridge and the printing process is enclosed, the potential for dermal exposure will be limited during printing. Local exhaust ventilation is used to minimise exposure to aerosols during industrial UV-cured inkjet printing. However, service technicians and office workers may be dermally exposed to the notified polymers at < 5% concentration on an infrequent basis when changing cartridges, removing waste boxes or during printer maintenance. Service technicians may wear gloves, though other workers are not expected to do so. Dermal exposure from contact with printed articles is not expected as the notified polymers will be bound to the article matrix when printed.

End use – automotive spraying

At end-use facilities, workers may be exposed to the notified polymer (at \leq 5% concentration), during transfer processes, mixing, application of the coatings and during cleaning and maintenance tasks. Exposure to the notified polymers is expected to be via the dermal and/or ocular routes. Inhalation exposure to the notified polymers is also possible during spray applications. The notifier states that exposure to the notified polymers is expected to be minimised through the use of PPE, including appropriate industrial clothing, eye protection and chemical resistant gloves (and respiratory protection during spray applications). The products are expected to be used in well ventilated areas and/or rooms fitted with fume extraction facilities.

6.1.2. Public Exposure

The ink products containing the notified polymers (at \leq 5% concentration) are intended for use in industrial settings and will not be sold to the public. The public may come into contact with the inks containing the notified polymers after application to substrates. However, once the inks are cured and dried, the notified polymers will be reacted and bound within a polymer matrix and will not be bioavailable.

6.2. Human Health Effects Assessment

As no toxicity data were provided, the notified polymers cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Reformulation

Reformulation workers have the highest potential for exposure to products containing the notified polymers (at <20% concentration). Exposure is mostly likely to occur via the dermal route, although ocular and inhalation exposure to the notified polymers may also occur. Although reformulation workers will handle the notified polymers frequently, inhalation exposure is expected to be minimised given the proposed use of PPE and largely enclosed, automated processes used in reformulation facilities. The risk to the health of reformulation workers is, therefore, not considered to be unreasonable, provided control measures are in place to minimise inhalation exposure (including the use of respiratory protection if ventilation is inadequate).

End use - printing

Workers with highest potential for exposure to products containing the notified polymers (at <5% concentration) include printer operators, technical staff and service technicians, when changing cartridges, removing waste boxes or during printer maintenance. Gloves may be worn by service technicians if performing regular printer maintenance operations. Exposure is most likely to occur via the dermal route. The potential for inhalation exposure will be minimised by the use of local exhaust ventilation.

The risk to workers is not considered to be unreasonable if such controls are in place.

End use – automotive spraying

When used for automotive spray paints there is the possibility of dermal, ocular and inhalation exposure to the notified polymers at < 5% concentration. These workers are expected to wear appropriate PPE including goggles, gloves and respiratory protection where ventilation is inadequate. In addition it is expected that engineering controls will minimise inhalation exposure. Therefore, provided exposure of workers to coating sprays is limited through the use of control measures (e.g. respirator and/or spray booths) and aerosol spray is

not used to apply the final product containing the notified polymers at < 5%, the risk to the health of workers is not considered to be unreasonable.

6.3.2. Public Health

The products containing the notified polymers will not be sold to the public. The public may have contact with the dried materials. However, once cured, the notified polymers will be reacted and bound within a polymer matrix and will not be bioavailable. Hence, public exposure to the notified polymer is not expected, and the risk to health of the public is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymers will not be manufactured in Australia. Therefore, release of the notified polymers from this activity is not expected. Reformulation of the notified polymers will take place in Australia. However, accidental spillage from this process is expected to be limited due to expected automated nature of the blending process which is typically in closed chambers. Potential release of the notified polymers to the environment during reformulation is estimated to be <0.5 kg per year.

RELEASE OF CHEMICAL FROM USE

The main release of the notified polymers from end-use as automotive coatings are expected as a result from overspray, spills, and leaks, from cleaning of equipment and from residues in empty containers. Spills and overspray are expected to be collected with absorbent material and/or engineering controls. The collected wastes and empty containers are expected to be disposed of to landfill. Up to 1% of import volume is expected to release to sewer during end-use due to equipment rinsing.

The main release of the notified polymers to the environment from end use as ink are expected from spills, wash-downs of printing equipment and from disposal of empty containers containing residual ink. The notified polymers are expected to be stable within an inert matrix on printed substrate once it is cured.

RELEASE OF CHEMICAL FROM DISPOSAL

Half of the paper that the notified polymers are bound to is expected to be recycled, which may result in the release of a proportion of the notified polymers to the aquatic compartment. Waste paper is pulped using a variety of chemical treatments that result in fibre separation and ink detachment from the fibres. The effluent is expected to be released to sewer. The reminder of printed paper is expected to be disposed of to landfill.

The notified polymers are expected to share the fate of the coated automobile parts, and at the end of the car's useful life, the coated metal articles will be sent to metal reclamation facilities or be disposed of to landfill. Residual notified polymers in empty import containers (1% of the total import volume) are expected to be disposed of to landfill during drum recycling.

7.1.2. Environmental Fate

The majority of the notified polymers are expected to enter the environment from disposal of printed paper products. Approximately 50% of printed articles containing the notified polymers are expected to be disposed of to landfill. Notified polymers in landfill are not expected to leach due to high adsorption/desorption ($K_{\rm OC}$) value and low water solubility, and are not expected to enter surface waters. When printed paper articles are subjected to recycling process, the notified polymers may partition to the supernatant liquid and be released as effluent. The notified polymers are expected to be removed during water treatment plant processes due to its low water solubility and high potential to sorb to sludge. Therefore, a small amount of the notified polymers from paper recycling may be released from treatment process to surface waters. Notified polymers that enter surface waters are expected to disperse and eventually degrade. Given that the notified polymers have high molecular weight, they are not expected to bioaccumulate as they are too large to cross the biological membranes.

During automotive paint application the notified polymers are expected to become irreversibly bound to form part of an inert coating matrix during the heat curing process. The notified polymers are expected to share the fate of the coated automotive parts, which will involve eventual disposal to landfill or thermal decomposition during metal reclamation. Notified polymers that are disposed of to landfill are expected to remain associated with the substrate to which they have been applied. In their cured form they are not expected to be mobile,

bioavailable or biodegradable. Ultimately, the notified polymers are expected to eventually degrade via biotic and abiotic processes in landfill, or by thermal decomposition during metal reclamation processes to form inorganic salts, water, and oxides of carbon, sulfur and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

Using a worst-case scenario, it is assumed that 100% of the notified polymers will be used in inks for printing on paper. It is further assumed that 50% of the paper products containing the notified polymers are expected to be recycled and the notified polymers will be released into sewers. As the notified polymers are to be processed at paper recycling facilities located throughout Australia, it is anticipated that such releases will occur on 260 days into the Australian effluent volume. The notified polymers are predicted to partition to sludge due to high adsorption/desorption (Koc) value and low water solubility. Therefore, the removal of 85% of the notified polymers from influent by sewage treatment plant (STP) processes is expected (Simple Treat; European Commission, 2003). The resultant estimate for the Predicted Environmental Concentration (PEC) in sewage effluent nationwide is presented below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment				
Total Annual Import/Manufactured Volume	30,000	kg/year		
Proportion expected to be released to sewer	50%			
Annual quantity of chemical released to sewer	15,000	kg/year		
Days per year where release occurs	260	days/year		
Daily chemical release:	57.69	kg/day		
Water use	150.0	L/person/day		
Population of Australia (Millions)	22.613	million		
Removal within STP	85%	Mitigation		
Daily effluent production:	3,392	ML		
Dilution Factor - River	1.0			
Dilution Factor - Ocean	10.0			
PEC - River:	2.55	μg/L		
PEC - Ocean:	0.26	μg/L		

Partitioning to biosolids in STPs Australia-wide may result in an average biosolids concentration of 144.57 mg/kg (dry wt). Biosolids are applied to agricultural soils, with an assumed average rate of 10 t/ha/year. Assuming a soil bulk density of 1,500 kg/m³ and a soil-mixing zone of 10 cm, the concentration of the notified polymers may approximate 0.964 mg/kg in applied soil. This assumes that degradation of the notified polymers occurs in the soil within 1 year from application. Assuming accumulation of the notified polymers in soil for 5 and 10 years under repeated biosolids application, the concentration of notified polymers in the applied soil in 5 and 10 years may approximate 4.82 mg/kg and 9.64 mg/kg, respectively.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1,000 L/m²/year (10 ML/ha/year). The notified polymers in this volume are assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m). Using these assumptions, irrigation with a concentration of 2.551 μ g/L may potentially result in a soil concentration of approximately 17.02 μ g/kg. Assuming accumulation of the notified polymers in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymers in the applied soil in 5 and 10 years may be approximately 85.04 μ g /kg and 170.1 μ g/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data for the notified polymers were submitted. Similar inkjet dyes are generally not harmful to fish and aquatic invertebrates (L(E)C50 > 100 mg/L), but can be moderately toxic to green algae. Effects on algae are mostly related to the colour of dyes, which can reduce the light needed for the algae's growth, rather than from direct toxic effects. Based on the algal toxicity found for similar polymers, the acute toxicity for algae is estimated to be greater than 1 mg/L for the notified polymers.

The estimation procedure used here is based on data for similar polymers and is considered acceptable for the purpose of risk assessment. However, this toxicity estimation is not considered sufficient to formally classify the acute and long term hazard of the notified polymers to aquatic life under the Globally Harmonised System for the Classification and Labelling of Chemicals (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The endpoint for the most sensitive species (algae) is used to calculate the predicted no-effect concentration (PNEC). An assessment factor of 100 was used as the endpoint for the most sensitive species is conservatively estimated.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Algae)	> 1	mg/L
Assessment Factor	100	
PNEC:	> 10	μg/L

7.3. Environmental Risk Assessment

Risk□Assessment	PEC μg/L	PNEC μg/L	Q
Q - River	2.55	> 10	< 0.255
Q - Ocean	0.26	> 10	< 0.026

The Risk Quotients (Q = PEC/PNEC) for the worst case discharge scenario have been calculated to be less than 1 for the river and ocean compartments. This indicates that the notified polymers are present in the environment at much lower concentrations than the concentration expected to cause adverse effects to aquatic organisms. Therefore, the notified polymers are not expected to pose an unreasonable risk to the aquatic environment based on their reported use pattern.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point > 450 °C

Method OECD TG 102 Melting Point/Melting Range.

EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature.

Remarks No significant protocol deviations

Test Facility Harlan (2012a)

Density $1.23 \times 10^{-3} \text{ kg/m}^3 \text{ at } 20 \text{ }^{\circ}\text{C}$

Method OECD TG 109 Density of Liquids and Solids.

EC Council Regulation No 440/2008 A.3 Relative Density.

Remarks No significant protocol deviations

Test Facility Harlan (2012a)

Vapour Pressure $1.5 \times 10^{-15} \text{ kPa at } 25 \text{ °C}$

Method OECD TG 104 Vapour Pressure.

EC Council Regulation No 440/2008 A.4 Vapour Pressure.

Remarks No significant protocol deviations. Determined using a vapour pressure balance.

Test Facility Harlan (2012b)

Water Solubility 1.25×10^{-3} g/L at 20 °C

Method OECD TG 105 Water Solubility.

EC Council Regulation No 440/2008 A.6 Water Solubility.

Remarks Column Elution Method

Test Facility Harlan (2012a)

Partition Coefficient (noctanol/water)

 $\log Pow = 3.43-6.47 \text{ at } 20 \, ^{\circ}\text{C}$

tanoi/watei j

Method OECD TG 107 Partition Coefficient (n-octanol/water).

EC Council Regulation No 440/2008 A.8 Partition Coefficient.

Remarks Shake Flask Method

It was not possible to manipulate the pH of the aqueous phase to obtain an un-ionised, molecular form for the partition coefficient test. Therefore, the definitive test was performed without any pH adjustment.

Although the HPLC estimation method (OECD 117) is the preferred method for the determination of partition coefficient for mixtures, it was not valid for these test substances in the absence of a mobile phase pH where an un-ionised, molecular form could be achieved for analysis. Therefore, it was concluded that the shake-flask method results were influenced by at least one component with differing solubility/partitioning characteristics to a majority of the test substances as a whole. Overall therefore, it was recognised that the test substances had the potential to present a highly hydrophobic character, with an apparent log

Kow of at least 6.47.

Test Facility Harlan (2012a)

Particle Size

Method OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions.

Range (μm) Mass (%)
< 100 1.7%

Remarks Only a 100 µm sieve was used. No other significant protocol deviations.

Test Facility Harlan (2012a)

Flammability Not highly flammable

Method EC Council Regulation No 440/2008 A.10 Flammability (Solids).

Remarks No significant protocol deviations

Test Facility Harlan (2012b)

Autoignition Temperature 269 °C

Method EC Council Regulation No 440/2008 A.16 Relative Self-Ignition Temperature for Solids.

Remarks No significant protocol deviations.

Test Facility Harlan (2013)

Explosive Properties Predicted negative

Method EC Council Regulation No 440/2008 A.14 Explosive Properties.

Remarks Decomposition onset temperature is above 500°C. No significant protocol deviations.

Test Facility Harlan (2013)

Oxidizing Properties

Method EC Council Regulation No 440/2008 A.17 Oxidizing Properties (Solids).

EC Council Regulation No 440/2008 A.21 Oxidizing Properties (Liquids).

Remarks

Test Facility Harlan (2013)

BIBLIOGRAPHY

- European Commission (2003). Technical Guidance Document on Risk Assessment in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances and Directive 98/8/EC of the European Parliament and of the Council Concerning the Placing of Biocidal Products on the Market Part II. Institute for Health and Consumer protection, European Chemicals Bureau, European Communities.
- http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/doc/tgd. Accessed on 27 February 2014.
- Harlan (2012a) Determination of General Physico-Chemical Properties (Project No. 41104078, April, 2012). Derbyshire, U.K., Harlan Laboratories Limited (Unpublished report submitted by the notifier).
- Harlan (2012b) Determination of Hazardous Physico-Chemical Properties (Project No. 41104079, June, 2012). Derbyshire, U.K., Harlan Laboratories Limited (Unpublished report submitted by the notifier).
- Harlan (2012c) Determination of Hazardous Physico-Chemical Properties (Project No. 41104079, June, 2012). Derbyshire, U.K., Harlan Laboratories Limited (Unpublished report submitted by the notifier).
- Harlan (2013) Determination of Hazardous Physico-Chemical Properties (Project No. 41205837, April, 2013). Derbyshire, U.K., Harlan Laboratories Limited (Unpublished report submitted by the notifier).
- NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
- United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), http://www.unece.org/trans/danger/publi/ghs/ghs rev03/03files e.html >.