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

PUBLIC REPORT

Chemical in SunCure Starlux and Solarflex Nova Inks

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/1721	DIC Australia Pty Ltd	Chemical in SunCure Starlux and Solarflex Nova Inks	ND*	< 1 tonne per annum	Component of industrial inks

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

As no toxicity data were provided, the notified chemical 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 chemical is not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment

On the basis of the PEC/PNEC ratio and the assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Health Surveillance

- As the notified chemical is a potential skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following isolation and engineering controls to minimise occupational exposure to the notified chemical:
 - Enclosed, automated processes, where possible
 - Local exhaust ventilation
- 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 chemical:
 - Avoid contact with skin
- 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 chemical:
 - Coveralls

- Impervious gloves

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

- A copy of the (M)SDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical 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

- Where reuse or recycling are not appropriate, dispose of the notified chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment, 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 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 importation volume exceeds one tonne per annum notified chemical;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from a component of industrial inks, or is likely to change significantly;
 - the amount of chemical being introduced has increased, or is likely to increase, significantly;
 - 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.

Material Safety Data Sheet

The MSDS of the product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

DIC Australia Pty Ltd (ABN: 12 000 079 550)
323 Chisholm Rd
Auburn NSW 2144

NOTIFICATION CATEGORY

Limited-small volume: Chemical other than polymer (1 tonne or less per year).

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, degree of purity, impurities, additives/adjuvants, use details and import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as for all physico-chemical endpoints

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

SunCure Starlux and Solarflex Nova Inks (containing the notified chemical at < 5% concentration)

MOLECULAR WEIGHT

< 500 Da

ANALYTICAL DATA

Reference HPLC, IR and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: clear yellow liquid

Property	Value	Data Source/Justification
Melting Point	~16 °C	SDS
Boiling Point	257.4 °C	SDS
Density	1,130 kg/m ³ at 20 °C	SDS
Vapour Pressure	2.1 × 10 ⁻⁷ kPa at 25 °C	SDS
Water Solubility	0.02 g/L at 20 °C	Calculated. WSKOW v1.42, EPI Suite v4.1 (US EPA, 2010).
Hydrolysis as a Function of pH	Not determined	Expected to slowly hydrolyse under ambient environmental conditions
Partition Coefficient	log Pow = 3.1	Calculated. KOWIN v1.68, EPI Suite v4.1 (US EPA, 2010)
Adsorption/Desorption	log Koc = 1.9 (MCI method) log Koc = 2.2 (Kow)	Calculated. KOCWIN v2.0, EPI Suite v4.1 (US EPA, 2010).

	method)	
Dissociation Constant	Not determined	Does not contain dissociable functionality
Flash Point	144 °C (closed cup)	SDS
Autoignition Temperature	423 °C	SDS
Explosive Properties	Predicted negative	Based on chemical structure
Oxidising Properties	Predicted negative	Based on chemical structure

DISCUSSION OF PROPERTIES

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

Reactivity

The notified chemical is 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 chemical is 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 chemical will be imported at < 5% in ink formulations.

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

PORT OF ENTRY

Sydney and Melbourne

IDENTITY OF RECIPIENTS

DIC Australia Pty Ltd

TRANSPORTATION AND PACKAGING

The notified chemical will be transported in the original import containers (3 kg or 10 kg plastic tubs) by road.

USE

The notified chemical will be used at < 5% concentration in UV curable lithographic inks designed for outer surface printing of carton board and foil boards, selected plastics and non-absorbent substrates as well as printing of labels, sleeves, tags and tickets or UV flexographic inks intended for the printing of labels, tags, sleeves, tickets and other applications found in the narrow web market. Printing on recyclable paper substrates is expected to account for approximately 50% of the import volume.

OPERATION DESCRIPTION

The notified chemical will not be manufactured, reformulated or repackaged in Australia.

At the end-use industrial UV printing companies, the ink formulations containing the notified chemical at < 5% concentration will be manually poured into ink reservoirs of the printing machines. While UV-printers are running, printer operators will monitor their operation and keep the substrate feeders stocked and attend to substrate jams.

Throughout the print run, quality control will be carried out by printer operators. Any residual ink within printing equipment will be wiped clean using rags and solvents.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and storage	4-8	50
Quality control/chemists and technical service	0.5-6	25
Printer operators	1-2	25
Service technicians	8	200

EXPOSURE DETAILS

Dermal and possibly ocular exposure to the notified chemical (at < 5% concentration) may occur during printing, cleaning and maintenance of printers. Inhalation exposure is not expected given the low vapour pressure of the notified chemical. Direct exposure to the printing inks containing the notified chemical during printing is expected to be low given the printing process is expected to be mainly enclosed and automated. Worker exposure during manual handling of ink formulations may also occur. The notifier states that exposure is expected to be minimised through the use of PPE such as protective clothing, eye protection, impervious gloves and the employment of local exhaust ventilation in areas surrounding the printing machines.

Worker contact with printed products may occur. However, once the printing ink is cured, the notified chemical is expected to remain bound within the ink matrix and will not be bioavailable.

6.1.2. Public Exposure

The inks containing the notified chemical at < 5% concentration will not be sold to the public. Contact with printed products may occur. However, once the printing ink is cured, the notified chemical is expected to remain bound within the ink matrix and will not be bioavailable.

6.2. Human Health Effects Assessment

No toxicity data were submitted.

Toxicokinetics

Based on the low molecular weight (< 500 Da) and partition coefficient (log Pow = 3.1) of the notified chemical, passive diffusion across the gastrointestinal (GI) tract and dermal absorption may occur.

Acute toxicity

Based on the Safety Data Sheet (SDS) provided, the notified chemical is of low toxicity through the oral (LD50 > 5000 mg/kg bw, rat) and dermal (LD50 > 2000 mg/kg bw, rabbit) route. No acute inhalation study was provided.

Irritation and sensitisation

Based on SDS provided, the notified chemical is not irritating to the skin. No study on eye irritation was provided.

The notified chemical is classified as sensitising to the skin in the SDS. This classification is consistent with classification and labelling from the European Chemicals Agency (ECHA).

Repeated dose toxicity

No repeated dose toxicity was provided. The ECHA classification and labelling showed the notified chemical may cause damage to central nervous system through prolonged or repeated exposure if inhaled.

Health hazard classification

As no toxicity data were provided, the notified chemical 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

The notified chemical may be sensitising and may cause damage to central nervous system through prolonged or repeated exposure if inhaled.

Given the low use concentration of the notified chemical (< 5%) systemic toxicity from repeated exposure is not expected, however workers may be at risk of sensitisation. However, exposure to printer operators is expected to be limited by the largely automated and enclosed processes, exhaust ventilation and the use of PPE including protective clothing, eye protection and impervious gloves. Therefore, provided that the stated PPE is used and engineering controls are in place to limit exposure, the risk to the health of printer operators is not considered to be unreasonable.

6.3.2. Public Health

The notified chemical will be used in industrial settings only and will not be sold to the public. The public may come into contact with the printed products containing the notified chemical. However, once the notified chemical is cured, it will be bound within the ink matrix and will not be bioavailable. Therefore, when used in the proposed manner, the risk to public health 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 chemical will not be manufactured or reformulated in Australia. Therefore, release of the notified chemical to the environment from these activities is not expected.

RELEASE OF CHEMICAL FROM USE

The plastic ink tubs are designed to prevent leakage and will not be opened during use, installation or replacement. Therefore, release of the notified chemical to the environment from these activities is not expected under normal conditions. However, if leakage or spillage occurs, the ink containing the notified chemical is expected to be contained with absorbent materials and disposed of to landfill. The residual ink containing the notified chemical (1% of the total import volume) is expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Empty containers containing the notified chemical in ink are expected to be disposed of to landfill.

7.1.2. Environmental Fate

No environmental fate study was submitted. As the majority of the notified chemical is expected to be released to the atmosphere, the potential for the notified chemical to persist and experience long range transport was assessed (AOP Program v1.92; US EPA, 2011). The notified chemical is predicted to experience a half-life of 2.4 hours (assuming a 12 hour day). As such, it is expected that the notified chemical will undergo rapid degradation via reactions with OH-radicals, and will not experience long-range transport.

The notified chemical trapped in the ink matrices is expected to be disposed of to landfill along with the substrate to which the ink is applied. Given the calculated low water solubility, the notified chemical is likely to have low mobility from landfill. In landfill, the notified chemical is expected to slowly decompose by abiotic and biotic processes to form water and oxides of carbon and phosphorus.

A small proportion of the notified chemical may be released to sewer during paper recycling. Given the calculated low water solubility and moderate log K_{oc} values, some of the notified chemical is expected to partition to sludge during waste water treatment processes in sewage treatment plants (STPs). Therefore, some of the notified chemical is expected to still remain in waste water and be released to aquatic environments. Based on its low water solubility and moderate log P_{ow}, the notified chemical has potential to bioaccumulate. Ultimately, the notified chemical is expected to degrade via biotic and abiotic processes in the atmosphere and surface waters to form water and oxides of carbon and phosphorus.

7.1.3. Predicted Environmental Concentration (PEC)

Based on the reported use in printing, it is conservatively assumed that 100% of the total import volume of the notified chemical will be used in paper printing. Using a worst-case scenario, it is assumed that 50% of the paper products containing the notified chemical will be recycled and will be released to the sewer with no removal during recycling or STP processes. As the notified chemical is 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 resultant estimate for the predicted environmental concentration (PEC) in sewage effluent nationwide is summarised in the table below.

<i>Predicted Environmental Concentration (PEC) for the Aquatic Compartment</i>		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	500	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	1.92	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.43	µg/L
PEC - Ocean:	0.04	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m³). Using these assumptions, irrigation with a concentration of 0.425 µg/L may potentially result in a soil concentration of approximately 2.84 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 14.2 µg/kg and 28.4 µg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data for the notified chemical were submitted. The ecotoxicity effects of the notified chemical were predicted using Ecological Structure Activity Relationships (ECOSAR v1.11, US EPA 2012). The conservative toxicity results are summarised in the table below.

Endpoint	Result	Assessment Conclusion
Fish	LC50 (96 h) > 2.1 mg/L	Expected to be toxic to fish
Daphnia	LC50 (48 h) > 1.3 mg/L	Expected to be toxic to aquatic invertebrates

The ECOSAR estimation endpoints indicate that the notified chemical is potentially toxic to fish and aquatic vertebrates. However, the actual toxicity of the notified chemical to aquatic life may be overestimated by the ECOSARs estimates derived here as surface waters tend to have higher total organic content (TOC) and dissolved organic content (DOC) than what is used in standard aquatic toxicity testing media. Classification should be based on actual toxicity endpoints and, therefore, the notified chemical cannot be formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The predicted endpoint for the most sensitive species (daphnia, EC50) was used to calculate the predicted no-effect concentration (PNEC) for the notified chemical. An assessment factor of 1000 was used as measured ecotoxicological endpoints were not available for the notified chemical.

<i>Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment</i>		
EC50 (Invertebrates).	1.3	mg/L
Assessment Factor	1,000	
PNEC:	1.3	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient values have been calculated as follows:

<i>Risk Assessment</i>	<i>PEC µg/L</i>	<i>PNEC µg/L</i>	<i>Q</i>
Q - River:	0.43	1.3	0.327
Q - Ocean:	0.04	1.3	0.033

The Risk Quotients ($Q = PEC/PNEC$) for a conservative discharge scenario have been calculated to be < 1 for the river and ocean compartments. The notified chemical is expected to slowly degrade in these water environments. Based on the short half-life of the notified chemical in air, it is not expected to pose an unacceptable risk in this compartment. Based on the assumed low hazard and the assessed use pattern of the notified chemical, it is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES**Explosive Properties**

Method	EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks	Predicted negative based on the chemical structure and oxygen balance
Test Facility	Chemicalia (2013)

Oxidizing Properties

Method	EC Council Regulation No 440/2008 A.21 Oxidizing Properties (Liquids).
Remarks	Predicted negative based on chemical structure
Test Facility	Chemicalia (2013)

BIBLIOGRAPHY

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>.