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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

IRR 260

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Director
NICNAS

TABLE OF CONTENTS

FULL PUBLIC REPORT

IRR-260

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Cytec Australia Holdings Pty Ltd (ABN: 45 081 148 629)
Suite 1, Level 1 Norwest Quay
21 Solent Circuit, Norwest Business Park
Baulkham Hills NSW 2153

NOTIFICATION CATEGORY
Limited: Polymer with NAMW ≥ 1000 (greater than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical Name
Other Name(s)
CAS Number
Molecular and Structural Formula
Molecular Weight
Spectral Data
Polymer Constituents
Residual Monomers/Impurities
Additives/Adjuvants
Purity
Hazardous Impurities
Non-Hazardous Impurities
Import Volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Boiling Point
Vapour Pressure
Hydrolysis as a function of pH
Adsorption/Desorption
Dissociation Constant
Flammability Limits
Autoignition temperature
Explosive Properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US PMN (1997)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
IRR-260

METHODS OF DETECTION AND DETERMINATION

ANALYTICAL METHOD	Gel Permeation Chromatography
Remarks	A reference spectrum was provided.

ANALYTICAL METHOD	IR Spectrum
Remarks	A reference spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY
55-65%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
The notified polymer contains 35-45% of a low molecular weight impurity (MW < 1000) with irritant and potential sensitisation effects.

DEGRADATION PRODUCTS
The notified polymer is not expected to degrade under normal conditions of use.

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
No loss of monomers, reactants, or impurities is expected under normal conditions of use due to the high molecular weight and expected low vapour pressure.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will be imported at a concentration of 100% as IRR 260.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-30	10-30	30-100	30-100	30-100

USE
The notified polymer is used as a UV/EB (Ultraviolet/Electron Beam) curable resin for coatings and printing inks and varnishes.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Reformulation will take place at specific high-end ink or coatings manufacturers. The reformulated products will be sold to printers and coaters across Australia.

TRANSPORTATION AND PACKAGING
The notified polymer is imported as IRR-260 (100%) in either 25 kg open top steel pails or 200 kg steel drums. The reformulated products will be packed into 5 kg and 25 kg open top steel pails or 200 kg closed top drums.

5.2. Operation description

The notified polymer is not manufactured in Australia.

Reformulation

As required the drums of IRR 260 will be transported by forklift from the warehouse to the production area. The notified polymer IRR 260 will be manually weighed and manually poured into a blending tank. After mixing with other desired ingredients the reformulated product containing up to 30% of the IRR 260 is manually packed into steel pails or drums and distributed to end-users. The notifier states that the reformulation process is not normally automated or enclosed. Drum and pail filling may be either automated or manual.

The formulated UV/EB curable products containing IRR 260 may be used for a number of applications and applied by a number of methods outlined below. No specific end-user has been identified as the product is recommended for a number of uses; hence detailed information on the application of products containing the notified polymer in coating and printing applications were not provided.

End-Use - Coating Applications

1. *Roller coating, Flow/Curtain coating, Spray coating*

At the application sites, the coating will be stirred, poured into trays and applied either by rollers or using flow/curtain coating techniques. Alternatively the coating will be poured into a spray gun for spray application purposes. Mixing and spraying is conducted in spray booths where the overspray is collected within the spray booth by its filtering system. After the coating is complete, the spray gun and lines will be emptied and any residual coating will be placed into waste drums for recycling. The spray gun is then cleaned at a recycled solvent wash station.

End-Use - Printing Applications

The following information on printing applications (except for gravure printing) is taken from a NICNAS chemical assessment report for a UV curing ink ingredient (NICNAS, 2000). Gravure printing operations are expected to be similar.

1. *Lithographic, flexographic and gravure printing*

Lithographic, flexographic and gravure printing are largely automated. A typical printing process involves charging the print machine, running the print and distributing the end product. In larger scale operations the inks could be fed to the print machine directly from the bulk containers under some form of controlled pressure. Excess ink is then returned to the same bulk container. Some on-site blending of inks may occur by computer controlled dispensing and metering equipment. The smaller operations may involve hand filling of the print machine reservoir from a small ink container.

2. *Screen printing*

Screen printing processes generally include printing and cleaning of the equipment and may include colour mixing. Mixing if required generally occurs in small containers using hand held mixers although mechanical stirrers are used for mixing larger quantities. The inks are applied by spatulas manually on to the ink trays of the machine or silkscreen. When the colour is changed, the leftover ink is scraped off the trays using spatula and returned to the ink storage area.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and Storage	5	1-5 h/day	10 days/yr
Reformulation	3	8 h/day	60 days/yr
Cleaning	4	0.5 h/day	12 days/yr
Quality control (application testing)	2	2 h/day	6 days/yr
End-Users (Coating and Ink application)	25	3 h/day	250 day/yr

Exposure Details

Transport and storage

Exposure to the notified polymer is not expected during the importation, warehousing or transportation of the notified polymer or the coating and ink products, except in cases where the packaging is accidentally breached.

Reformulation
Skin contact with IRR 260 may occur during weighing of the notified polymer and transfer of the notified polymer to the blending vessel. All operations involving transfer are expected to be carried out under exhaust ventilation.

Blending of the notified polymer into finished coatings and inks varies depending on the customer's facility. Dermal or ocular exposure to IRR 260 (< 30% concentration) is possible during manual packaging. It is expected that blending would occur under local exhaust ventilation. Exposure during an automated repacking process would be limited to accidental spillage.

Workers involved in reformulation typically wear overalls, gloves and safety glasses.

Incidental skin contact with IRR 260 (< 30% concentration) may occur during sampling and analytical and quality control procedures. A number of quality control tests are required for printing inks. Workers may also be exposed to the polymer via the dermal and ocular routes while cleaning and rinsing process equipment.

Coating Application
Dermal and potential ocular exposure to IRR 260 (< 30% concentration) could occur during stirring, transfer to trays or application. Additionally, inhalation exposure (due to aerosols formed) during spray application may be possible. The product is stirred and sprayed in booths with an exhaust/filter system, and workers wear air-fed respirator safety glasses, gloves and overalls.

Workers may also be exposed to the polymer via the dermal and ocular routes while cleaning and rinsing coating application equipment.

Printing Ink Application
Dermal exposure to the IRR 260 (< 30% concentration) could occur when opening and handling ink containers, when mixing the ink (screen printing), when introducing the ink into the print machine (especially in the case of screen printing and small lithographic and flexographic printing operations), from intermittent contact with printing rollers/heads and from cleaning operations and contact with contaminated rags. Suitable gloves are expected to be used in all these operations.

5.4. Release

RELEASE OF CHEMICAL AT SITE
The notified polymer will be manufactured overseas, so there will be no release due to this activity in Australia. Local operations will include transport and storage, reformulation, filling and packaging and application by end-users.

During storage and coating and ink manufacture the notified polymer will be released in the following ways:

Spills	- up to 1%
Import container residue	- up to 1%
Process equipment cleaning	- up to 1%.

It is anticipated that there will be minimal release of the notified polymer during manual transfer from the storage containers to the mixers and during end user container filling or during blending. Spills will be contained by bunding, collected with inert absorbent material (eg sand) and placed in a sealable container ready for disposal. Spilt material may also be reused if not contaminated.

Since the coating and ink requires UV to cure, the process equipment (including tanks, mixers and transfer lines) is not cleaned between batches but rather when batch formulations change. At this stage the lines etc are drained and the material drummed and stored for recycling. The process equipment will then be cleaned with a suitable solvent which is collected and reused if possible, otherwise it will be disposed of via a licensed waste contractor. Import containers will be rinsed with the rinsate being used in the coating formulation and the rinsed containers will be recycled.

RELEASE OF CHEMICAL FROM USE

The coatings and inks containing the notified polymer will only be used by industry. Release of the notified polymer to the environment as a result of coating and ink use is expected to be minimal, unless an accidental spillage occurs, and include:

Spills	- up to 1%,
Container residue	- up to 1%
Application equipment cleaning and overspray	- up to 5%

If accidental spillage occurs during normal operating procedures at the end-user's site, it will be contained and soaked up with inert absorbent material (sand) and placed in a sealable container for disposal, generally to landfill.

The empty containers are rinsed with solvents, before collection by waste disposal contractors. The used solvent will be collected and disposed of via a licensed waste contractor.

The coatings and inks may be applied via a number of methods. Due to the fact that the coating and ink requires UV to cure, any excess coating will be collected and recycled. The application with the greatest potential loss is spray application of coatings. There will be an overspray of up to 50% but much of this (approximately 90%) will be recycled, thus approximately 5% may be disposed of. Application equipment is cleaned with a suitable solvent when there is a change in the colour of the coating being applied. The used solvent is collected and sent to a licensed liquid waste disposal contractor. As it is not possible to determine how much of the notified polymer will be applied via each method, it is estimated as a worst case scenario that 5% will be lost due to application and equipment cleaning. There will be no release to sewer.

5.5. Disposal

Spilt material and solid waste generated due to overspray will be disposed of to landfill. The other wastes streams during reformulation and application will be disposed of via licensed waste contactors, either for solvent recovery or drum recycling, with any resultant solids disposed of to landfill. Incineration is also a possibility with the destruction of the polymer and generation of water and oxides of carbon and nitrogen.

The majority of the notified polymer will be disposed of with the coated or printed article at the end of its useful life. As some of the coatings and inks containing the notified polymer will be used for printing on paper, the routes of disposal may include paper recycling.

5.6. Public exposure

Coatings and printing inks are applied under controlled conditions in industrial plants. Public exposure to the notified polymer is only likely after the coating or ink applied to the articles has fully dried. The notified polymer forms a film on the coated or printed article and is unavailable for exposure.

6. PHYSICAL AND CHEMICAL PROPERTIES

The notified polymer, as introduced, contains a significant amount of a low molecular weight impurity. Limited physicochemical data has been provided for the notified polymer at a purity of 55-65%. The presence of this unreacted starting material is expected to affect these properties.

Appearance at 20°C and 101.3 kPa	Clear pale liquid
Boiling Point	> 100°C at 101.3 kPa (estimated)
Remarks	No study was conducted. Estimated based on boiling points of residual monomers and process solvents. It is expected that the polymer would polymerise before reaching its boiling point.

Density 1125 kg/m^3 at 23°C

METHOD In-house method
Remarks The density was measured using a picnometer.
TEST FACILITY Cytec (2006)

Vapour Pressure < 0.133 kPa at 20°C (estimated)

Remarks No study was conducted. The vapour pressure of the notified polymer is expected to be low given the high molecular weight.

Water Solubility Not readily soluble

METHOD In-house method
Remarks 100 mL of the notified polymer was added to 1 L of water and stirred for 24 hours and left to stand for 2 hours. The notified polymer formed an emulsion with water on mixing with both the aqueous layer and polymer layer still hazy after 2 hours standing. The level of the notified polymer had increased after mixing indicating that some water had been absorbed by it. Therefore, the notified polymer is not readily soluble.
TEST FACILITY Cytec (2005)

Hydrolysis as a Function of pH Not determined

Remarks The notified polymer is not soluble in water.

Partition Coefficient (n-octanol/water) Not determined

Remarks The notified polymer is not soluble in water.

Adsorption/Desorption Not determined

Remarks The notified polymer is not soluble in water.

Dissociation Constant Not determined

Remarks The notified polymer is not soluble in water.

Particle Size Not applicable.

Flash Point > 100°C (estimated)

Remarks No study was conducted. A flash point of > 100°C is reported to be common for radiation curable products of low vapour pressure and low content of volatile components.

Flammability Limits Not determined.

Remarks Based on the flash point, the notified polymer is not classified as a flammable liquid according to the Australian Dangerous Goods Code (FORS, 1998).

Autoignition Temperature Not determined.

Remarks Not expected to autoignite.

Explosive Properties Not determined.

Remarks The notified polymer does not contain functional groups that would imply explosive properties.

Reactivity

Remarks — The notified polymer should not be stored at temperatures exceeding 60ºC and should not be exposed to direct sunlight. The notified polymer is reactive in the presence of a photoinitiating agent and UV or EB radiation, hazardous polymerisation could occur under these conditions.

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral	LD50 > 2000 mg/kg bw, low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating

7.1. Acute toxicity – oral

TEST SUBSTANCE — Notified polymer (55-65% purity)

METHOD
- Species/Strain: Rat/Sprague-Dawley
- Vehicle: Notified polymer administered as supplied.
- Remarks - Method: Statement of GLP. No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 males	2000	0/5
II	5 females	2000	0/5

- LD50: > 2000 mg/kg bw
- Signs of Toxicity: Piloerection and increased salivation were observed in all rats within 5 minutes of dosing. Piloerection persisted and was accompanied in all rats at later intervals on Day 1, by an ungroomed appearance. All animals had fully recovered by Day 2. There were no remarkable body weight changes during the study period.
- Effects in Organs: No macroscopic findings were recorded at necropsy.

CONCLUSION — The notified polymer is of low toxicity via the oral route.

TEST FACILITY — Huntingdon (1994a)

7.2. Irritation – skin

TEST SUBSTANCE — Notified polymer (55-65% purity)

METHOD
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 3
- Vehicle: Notified polymer administered as supplied.
- Observation Period: > 2 hours
- Type of Dressing: Semi-occlusive.
- Remarks - Method: Statement of GLP. No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	0	-	-
Oedema	0	0	0	0	-	-

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

CONCLUSION The notified polymer is non-irritating to skin.

TEST FACILITY Huntingdon (1994b)

7.3. Irritation - eye

TEST SUBSTANCE Notified polymer (55-65% purity)

METHOD EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain Rabbit/New Zealand White

Number of Animals 3

Observation Period 7 days for two animals, 14 days for one animal

Remarks - Method Statement of GLP.
No significant protocol deviations.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	2	2	1	2	7-14 days	0
Conjunctiva: chemosis	2.3	1.3	0	3	7-14 days	0
Conjunctiva: discharge						0
Corneal opacity	1.3	1	0	2	7-14 days	0
Iridial inflammation	0	0	0	0	-	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results Corneal opacification and well-defined conjunctival irritation was observed in two animals. The third animal showed only very slight conjunctival irritation.

The notified polymer, as introduced, contains an impurity at 35-45% which is stated as an eye irritant on the product MSDS. Therefore the slight irritancy observed in this study could be due to the presence of this impurity. However, the possibility of irritancy effects due to the notified polymer can not be ruled out.

CONCLUSION The notified polymer is slightly irritating to the eye.

TEST FACILITY Huntingdon (1998)

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted.

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Due to its low water solubility, the notified polymer disposed of to landfill will not be mobile and will adhere to soil. In landfill it will slowly degrade due to biotic and abiotic processes.

The coating and ink will react under UV radiation to form an inert cross-linked coating, so that when the coated or printed article is disposed of to landfill at the end of its useful life, the notified polymer will not be released/available.

9.1.2. Environment – effects assessment

No ecotoxicity data were provided so a PNEC could not be determined. However, aquatic exposure is expected to be minimal during normal usage of the coating and inks. Aquatic toxicity is also likely to be limited by the expected low water solubility.

9.1.3. Environment – risk characterisation

In landfill, the notified polymer is expected to become associated with soil and sediment and slowly degrade through biotic and abiotic processes to water and oxides of carbon and nitrogen. If wastes are incinerated then the notified polymer would be destroyed with the production of water vapour, and oxides of carbon and nitrogen.

Furthermore, the limited exposure of the notified polymer to the aquatic compartment due to its low water solubility, expected strong adsorption to soil and the relatively high molecular weight, means that it is unlikely to have an adverse effect on aquatic organisms.

The majority of the notified polymer will be applied to surfaces and share the fate of the surface at the end of its useful life (most likely to landfill).

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport and storage

During transport and storage, workers are unlikely to be exposed to the notified polymer except when packaging is accidentally breached.

Reformulation

Dermal or ocular exposure to IRR 260 (100% or 30%) during the reformulation process is expected to be limited by the wearing of PPE by workers. Inhalation exposure is unlikely due to the predicted low vapour pressure of the notified polymer and the use of engineering controls such as local exhaust ventilation.

End-use

Dermal and ocular exposure to the IRR 260 (30%) during the handling of solutions for coating and printing applications is expected to be limited by the use of PPE. However, safety glasses may not be worn during all processes, particularly during printing applications. Dermal and inhalation exposure to aerosols formed during coating applications is expected to be limited by the use of a spray booth and the wearing of PPE, including air-fed respirators.

9.2.2. Public health – exposure assessment

Public exposure is expected to be negligible as the public only comes into contact with articles in which the notified polymer is cured and not bioavailable.

9.2.3. Human health - effects assessment

Acute toxicity

In an acute oral toxicity study conducted on the notified polymer (55-65% purity) an LD50 of > 2000 mg/kg bw was found. The notified polymer is therefore considered to be of low acute oral toxicity.

Irritation

Based on skin and eye irritation studies conducted on the notified polymer (55-65% purity), the notified polymer is considered to be non irritating to skin and slightly irritating to the eye.

The notified polymer, as well as the impurity, contains a structural alert for skin sensitisation. The sensitisation hazard is likely to be limited due to the high molecular weight (MW > 1000), and therefore low skin permeability, of the notified polymer. However sensitisation effects to the notified polymer as introduced, can not be ruled out due to the presence of the low molecular weight species and impurity (MW < 1000).

No other toxicological studies were submitted. Based on the high molecular weight of the notified polymer absorption across biological membranes will be limited, and systemic toxicity is therefore unlikely.

Based on the available data, the notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

9.2.4. Occupational health and safety – risk characterisation

Based on the low hazard of the notified polymer, as well as the limited worker exposure, the risk to occupational health and safety is expected to be low. However, the notified polymer was shown to have slight eye irritancy effects, and skin sensitisation effects could not be ruled out. Where dermal or ocular exposure to the notified polymer is possible, personal protective equipment (protective clothing, impervious gloves and safety glasses) would limit the risk of irritant/sensitisation effects. During spray application of the coating the risk of irritant/sensitisation effects would be limited by application in the spray booth and use of PPE.

9.2.5. Public health – risk characterisation

Public exposure to the notified polymer is expected to be negligible and therefore the risk to public health is also expected to be negligible.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

and

As a comparison only, the notified polymer is not classified as hazardous to health using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003). Since no ecotoxicity data was provided an environmental classification could not be determined. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

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

10.3.2. Public health

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

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified polymer provided by the notifier is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

A label for the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical in formulated coating products:
  - Spray application should be conducted in a down draft spray booth.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced, and as diluted for use in blended products:
  - Avoid skin and eye contact
  - Avoid breathing aerosol
  - Spray application of coatings containing the notified polymer should be accordance with the NOHSC National Guidance Material for Spray Painting (NOHSC, 1999)

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced, and as diluted for use in blended products:
  - Chemical resistant gloves
  - Protective clothing
  - Safety goggles
  - Suitable respirators during spray application

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

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

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

Environment

- The following control measures should be implemented by coating manufacturers and warehouse sites to minimise environmental exposure during coating formulation and storage of the notified polymer:
  − All process equipment and storage areas should be bunded.

Disposal

- The notified polymer should be disposed of to landfill for solids and to licensed waste contractors for liquids.

Emergency procedures

- Spills/release of the notified polymer should be contained by soaking up with inert absorbent material and disposed of as special waste in compliance with local and State regulations as recommended in the MSDS.
- Prevent product from entering drains.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act:
  − if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

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