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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Acrylate/Amine Adduct R-50481

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Acrylate/Amine Adduct R-50481

1. APPLICANT

3M Australia Pty Limited of 2-74 Dunheved Circuit ST MARYS NSW 2760 has submitted a limited notification statement in support of their application for an assessment certificate for Acrylate/Amine Adduct R-50481

2. IDENTITY OF THE CHEMICAL

Acrylate/Amine Adduct is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data and details of the chemical composition have been exempted from publication in the Full Public Report and the Summary Report.

Other names:	Acrylate/Amine Adduct R-50481
Trade name:	component of Scotchcal™ Screen Printing Ink

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	clear light yellow oily liquid with mild amine odour
Boiling Point:	>93°C (submitted estimate) 255°C (at 760 mm Hg, ASTER calculated (1))
Specific Gravity:	1.14
Vapour Pressure:	1.12×10^{-10} kPa at 25°C (ASTER calculated)
Water Solubility:	122 g/L (ASTER calculated)
Partition Co-efficient (n-octanol/water):	log P_{ow} = 1.16 log P_{ow} = 1.12 (ASTER calculated)
Hydrolysis as a Function of pH:	half life > 1000 days (ASTER calculated)
Adsorption/Desorption:	log K_{oc} = 1.95 (ASTER calculated)

Dissociation Constant:	pK_a = 5.70 at 25°C (ASTER calculated)
Flash Point:	not determined
Flammability Limits:	not determined
Autoignition Temperature:	not determined
Explosive Properties:	morpholine may evolve during combustion
Reactivity/Stability:	stable

Comments on Physico-Chemical Properties

The content of reported physico-chemical properties in the submission was limited as "the notified chemical is not imported by itself, but as a part of a complete mixture" and it was noted that there are no proposed releases of notified chemical to terrestrial or water environments. However, it is expected that the substance would be obtained commercially and added to the mixture in its own right and thus these data ought to have been available to the notifier. For this reason the information has been obtained from the ASTER database (1).

The notifier claims that the notified chemical is completely miscible in water at blends of 90/10, 50/50 and 10/90 (notified chemical to water by weight). This was determined by the notifier's research laboratories. This result is confirmed by the ASTER calculated values.

As the chemical is soluble in water and contains ester moieties, the chemical could hydrolyse under environmental conditions but exposure of the uncured notified substance to water is low and subsequently the potential for hydrolysis is negligible. This suggestion is in support of the ASTER calculated data.

The partition coefficient value submitted was calculated on a computer modeling program (a C Log P program) and compares closely with the value calculated by the ASTER database.

Adsorption/desorption information was not submitted for the diacrylate adduct but the notified substance is expected not to sorb strongly to soils given its high water solubility and low log P. Again this is supported by ASTER calculations.

The substance exhibits basicity typical of morpholines, and the ASTER calculated dissociation constant for the notified substance suggests that under normal environmental conditions, this substance is not expected to dissociate significantly.

4. PURITY OF THE CHEMICAL

Degree of purity: > 60%

5. USE, VOLUME AND FORMULATION

The Acrylate/Amine Adduct R-50481 is manufactured by the parent company in the United States. The substance will be used as a minor component of Scotchcal™ Screen Printing Ink. Less than 1000 kg per annum of the notified chemical is expected to be imported over the next five years.

6. OCCUPATIONAL EXPOSURE

The notified chemical formulated within the ink will be imported in 3.7 L plastic containers. There is not expected to be any exposure to transport workers, except in the event of a major spillage of the formulated inks containing the notified chemical.

The number of printing establishments that would utilise the screen printing ink cannot be determined. Up to two workers per screen printing establishment will manually mix and apply the formulated product to silk screens by squeegee for commercial productions. There is expected to be potential for exposure to the notified chemical in the inks for up to 8 hours a day. The silk screening is conducted at room temperature, normally with local exhaust ventilation. The silk screened films are subsequently placed onto a conveyor and fed into a UV-light exposure chamber (equipped with local exhaust ventilation) and exposed to ultraviolet light for a fraction of a second which allows the ink to cure. No further occupational exposure to the notified chemical on printed articles is expected after the ink cures. There may be further exposure to residual ink on the silk screen during cleaning with a lacquer thinner.

7. PUBLIC EXPOSURE

The potential for public exposure to Acrylate/Amine Adduct R-50481 during the silk screening process is considered to be low, due to the low volatility of the chemical and the use of UV exposure chambers equipped with local exhaust ventilation.

These inks are generally used only in commercial screen printing. The public will come into limited contact with silk screened items, and in these cases the Acrylate/Amine Adduct R-50481 will be irreversibly bound into the UV cured ink matrix. Minor public exposure may result from accidental spillage during transport and storage of the inks.

8. ENVIRONMENTAL EXPOSURE

Release

The price of these inks is high, so the company expects screen printers will maximise utilisation of any ink purchased. Silk screen printing involves controlled application of inks via ink-filled squeegees, which avoid ink waste. Following application, the printed substance is cured immediately and then stored for use. Subsequently, the quantity of the notified chemical contained in the waste from the silk screening process will be negligible. Potential losses might arise from the changing of application squeegees, changing of printing stencils, ink spills or incomplete curing. Each of these losses would be contained at the time of spillage. A commercial lacquer thinner, rather than water, is used as a cleaning solution. The notifier estimates the total amount of waste to be < 1% of the total ink. The recommended disposal method of this waste is by incineration.

The UV Ink is described as "solventless". In this context it means that there is no liquid (organic solvent or water) which must be removed from the mixture to take on its solidified form. An advantage of UV curing is a reduction in air pollution (2). Therefore there is essentially no release of ink constituents during the UV curing process.

Any spills of the products containing the notified chemical should be contained and covered with absorbent material. This should be collected, placed in a closed container and then sent for incineration.

Articles coated with the cured ink containing the notified chemical will be disposed of as solid waste in landfill.

Fate

As it will be incorporated in the matrix of the chemical, the fate of the notified substance is identical to that of the articles to which it is bound. These articles would eventually be disposed of to landfill. Here they would very slowly break down. It is unlikely that the cured ink would leach, but stay within the landfill.

For screen washup, commercial thinners are used. These wastes are then collected and sent for incineration. Complete incineration of the notified chemical will result in water, and oxides of carbon and nitrogen.

· Biodegradation

The biodegradation of the notified substance has been determined to negligible by the modified OECD screening test (3). This protocol determines the aerobic biodegradation potential of organic material by measuring the loss of dissolved organic carbon in these test systems over a period of 28 days. The notified adduct showed 11.1% biodegradation over the 28 day period which indicates the

substance is not readily degradable. Note that the ASTER database indicates a BOD half-life of between 2 and 15 days, indicating the substance is not highly persistent.

· Bioaccumulation

The notified substance is "completely" water soluble, has a low logP_{ow} value and a low potential for exposure to aquatic environments. These three features suggest that the potential of this substance to bioaccumulate is low. This is supported by a calculated BCF of 3 on the ASTER database. Further, since the waste generated by use of the notified substance will be incinerated, the potential of bioaccumulation is negligible and the only situation in which there would be any likelihood of bioaccumulation would be in the event of spillages.

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicological data are not required for limited notifications according to the Act. However, the following toxicological studies were provided for consideration.

Summary of the acute toxicity of Acrylate/Amine Adduct R-50481

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD_{50} > 2000 mg/kg	(4)
Acute dermal toxicity	Rabbit	LD_{50} > 2000 mg/kg	(5)
Skin irritation	Rabbit	not a skin irritant	(6)
Eye irritation	Rabbit	slight irritant	(8)
Skin sensitisation	Guinea pig	not a skin sensitiser	(9)

9.1.1 Oral Toxicity (4)

Sprague-Dawley rats (5 per sex) were administered a single gavage dose of 2000 mg/kg of the notified chemical. The animals were maintained for 14 days. Mortality and clinical signs of toxicity were assessed several times on the day of test compound administration, and twice daily (for mortalities) and daily (for clinical signs of toxicity) thereafter. Body weight was determined on days 1, 7 and 14. An autopsy was performed on all animals at the completion of the study.

No deaths were seen during the 14 day study. No clinical signs of toxicity were observed on any day. There were no compound related findings at necropsy. The acute oral LD_{50} of the notified chemical was greater than 2000 mg/kg in male and female rats.

9.1.2 Dermal Toxicity (5)

The following study was not conducted to Good Laboratory Practice standard.

A dose of 2000 mg/kg of the notified chemical was applied to shaved, intact skin of New Zealand albino rabbits (5 per sex). The area was occluded for 24 hours, after which the impervious wrapping was removed and the residual chemical removed by washing with soap and water. The study was terminated after 14 days. Mortality and clinical signs of toxicity were assessed daily. Body weight was determined on days 0 and 14. An autopsy was performed on all animals at the completion of the study.

No deaths, abnormal clinical signs or evidence of skin irritation were noted during the study other than one female with focal alopecia appearing on day 13, and one male with a fluid filled kidney seen at autopsy. The acute dermal LD_{50} of the notified chemical was greater than 2000 mg/kg in male and female rabbits.

9.1.3 Inhalation Toxicity

Not done

9.1.4 Skin Irritation (6)

The fur was clipped from the back of 3 New Zealand White rabbits (2 females, 1 male), and 0.5 mL of the notified chemical was applied to the intact skin for 4 hours under semi-occlusive dressing. Residual chemical was then removed by washing with water. Animals were examined daily for clinical signs of toxicity. Body weight was determined the day of chemical application. Skin reactions were assessed approximately 30 minutes, 24, 48 and 72 hours after chemical removal. The severity of the reactions were determined by the degree of erythema and oedema, as described by Draize (7).

No dermal irritation was seen in any animal during the study period. The notified substance was not a dermal irritant in rabbits.

9.1.5 Eye Irritation (8)

A dose of approximately 0.1 mL of the notified chemical was instilled into the conjunctival sac of one eye of 3 female New Zealand White rabbits. Body weight was determined on the day of application. The eyes were examined 1, 24, 48 and 72 hours after chemical instillation, and the degree of irritation assessed using the Draize (7) method. A sodium fluorescein solution was used to assess the presence and severity of corneal damage at preinitiation and 72 hours after chemical instillation.

One animal exhibited excessive pawing at the dosed eye immediately after administration and contributed the total Draize score of 4 at one hour for conjunctival reddening and chemosis. The mean total Draize score (average for 3 animals) was 1.3 after 1 hour, and 0 at all other times. No corneal or iridial irritation was exhibited by any

animal during the study period. The fluorescein examinations were all negative. The notified chemical was a slight ocular irritant in rabbits.

9.1.6 Skin Sensitisation (9)

Four albino guinea pigs were used in a preliminary induction dose finding study. Subsequently, thirty albino guinea pigs were divided into a vehicle control group (n = 10, 2 males, 8 females) and a treatment group (n = 20, 4 males, 16 females). The hair was removed from a region along the midline over the shoulder region. On day 1, animals in the test group received duplicate 0.1 mL intradermal injections over the shoulder area of a 1:1 ratio of Freunds Complete Adjuvant in sterile water, a 5% w/v suspension of R-50481 in distilled water and a 5% w/v suspension of R-50481 in Freunds Complete Adjuvant and sterile water. On day 1, animals in the vehicle control group received duplicate 0.1 mL injections of Freunds Complete Adjuvant in sterile water, deionized water alone, and a 1:1 ratio of deionized water in Freunds Complete Adjuvant. On day 8, the animals in both groups received a topical application of the respective test or control materials under 48-hour occluded conditions. Two weeks after the topical application, all animals in both groups received a challenge dose. The undiluted test material was applied to the right flank of test and vehicle control animals. The left side of each animal was treated with deionized water. All test sites were occluded for 24 hours and then wiped clean. Test sites were examined for erythema and oedema at 24 and 48 hours after patch removal. The animals were observed for clinical signs daily throughout the study. Body weights were determined before test material administration (Day 1) and at days 8, 15 and 22, and at termination of the experimental phase (Day 26).

None of the test or vehicle control animals exhibited a dermal reaction to the challenge application of the test or vehicle control materials. The notified substance is not considered to be a skin sensitiser in guinea pigs when tested by the Magnusson and Kligman (10) maximisation assay.

9.2 Repeated Dose Toxicity

Not submitted

9.3 Genotoxicity

9.3.1. Salmonella typhimurium Reverse Mutation Assay (11)

In the Ames test using *Salmonella typhimurium* bacteria, strains TA1535, TA1537, TA1538, TA98 and TA100, the notified chemical in aqueous solution, at concentrations of 312 - 5000 µg/plate, and in the presence or absence of rat liver S9 (Araclor 1254 induced), failed to induce a dose-related increase in the number of reverse mutations. The positive controls used without metabolic activation were ethyl-nitro-nitrosoguanidine in DMSO (TA1535, TA100), 9-aminoacridine in DMSO (TA1537), 2-nitrofluorene in DMSO (TA1538, TA98) , and with metabolic activation was 2-aminoanthracene in DMSO (all

strains). The positive controls significantly increased the number of revertants and indicated that the assay functioned correctly.

9.3.2. Escherichia coli Reverse Mutation Assay (11)

In the reverse mutation assay using *Escherichia coli*, strain WP2*uvr*A, the notified chemical in aqueous solution, at concentrations of 312 - 5000 µg/plate, and in the presence or absence of rat liver S9 (Araclor 1254 induced), failed to induce a dose related increase in the number of reverse mutations. The positive control used without metabolic activation was ethyl-nitro-nitrosoguanidine in DMSO , and with metabolic activation was 2-aminoanthracene in DMSO. The positive controls significantly increased the number of revertants and indicated that the assay functioned correctly.

9.3.3. Chromosomal Aberrations in Cultured Human Peripheral Lymphocytes (12)

The notified chemical, when examined at concentrations ranging from 625 to 5000 µg/mL with S9 activation, and at 78 to 625 µg/mL without S9 activation, did not induce clastogenicity in cultured human lymphocytes after 24 and 48 hours. The positive control chemicals, ethyl methanesulphonate and cyclophosphamide, produced a significant increase in the incidence of cells with chromosomal aberrations.

9.4 Overall Assessment of Toxicological Data

The notified chemical is considered to be non-irritating to the skin and a slight eye irritant of rabbits. The substance has low acute oral and dermal toxicity in rats and rabbits respectively (LD_{50} > 2000 mg/kg), and is not a skin sensitiser in guinea pigs nor a mutagen in bacterial tests. There were no repeat dose or *in vivo* genotoxicity studies submitted with this notification. The notified chemical has been shown to have little interaction with biological material, and the absence of *in vivo* genotoxicity studies in this case, is not likely to be a cause for concern in occupational or public health assessment.

The notified chemical is not classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (13).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data are required for chemicals with an annual import rate of < 1 tonne according to the Act.

However, investigations into the acute toxicity of the notified substance to *Daphnia magna* were reported. These tests determine EC_{50} levels of the toxicant during a 48 hour exposure period, according to procedures formulated by the American Society for Testing and Materials (14) and the US Environmental Protection Agency (15). No abnormal effects were observed in any of the tests and the results of these studies indicated a 48 hour EC_{50} > 1000 mg/L. At these levels the

acrylate/amine adduct would be considered practically non-toxic.

The ASTER database contains a calculated LC_{50} value of 48.6 mg/L for the flathead minnow, suggestive of slight toxicity to fish.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The very low environmental exposure of the substance as a result of normal use indicates that the overall environmental hazard should be negligible.

The cured ink will be inert and bound to the article which it coats. Articles coated with printing inks containing the notified chemical are expected to be disposed of to landfill. The environmental hazard from the disposal of the product containing the substance is rated as negligible.

Complete incineration of the notified chemical will generate oxides of carbon and nitrogen, and water. The environmental hazard can be rated as low.

The only sources of environmental contamination during normal usage are from accidental spills, etc. The Material Safety Data Sheet (MSDS) is adequate to limit the environmental exposure from such events.

The overall environmental hazard can be rated as low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is not expected to be toxic to humans by oral or dermal administration, nor is it expected to be a skin or eye irritant. There is not expected to be any sensitising properties, nor is the notified chemical expected to exhibit any mutagenic properties. The notified chemical is not classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (13).

There is likely to be the risk of dermal exposure to the notified chemical from splashing or spillage through the work practices of mixing and applying the ink to silk screens prior to curing through UV exposure. To prevent exposure to the notified chemical within the ink formulation safety goggles, protective clothing and impervious gloves should be utilised but cannot be guaranteed in commercial application. Use of the final formulated ink may require the use of an organic vapour respirator, which will also serve to reduce exposure to the notified chemical.

There is no significant occupational health risk from the notified chemical, however the notified adduct will be formulated in screen printing inks which are likely to be occupational health risks due to their potential eye, skin and respiratory irritation properties.

The chemical is a minor component of screen printing inks, the use of which is generally restricted to commercial premises. Given the limited nature of public exposure to this substance, significant health effects are unlikely.

13. RECOMMENDATIONS

To minimise occupational exposure to Acrylate/Amine Adduct R-50481 the following guidelines and precautions should be observed:

- If engineering controls and work practices are insufficient to reduce exposure to Acrylate/Amine Adduct R-540481 to a safe level, then the following personal protective equipment which conforms to Australian Standards (AS) or Australian/New Zealand Standards (AS/NZS) should be worn;

  safety goggles should be selected and fitted in accordance with AS 1336 (17) to comply with AS/NZS 1337 (18),

  industrial clothing must conform to the specifications detailed in AS 2919 (19),

  impermeable gloves or mittens conforming to AS 2161 (20)

- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (20).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

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2. Oil and Colour Chemists' Association, Australia 1984, *Surface Coatings. Volume 2 - Paints and Their Applications*, TAFE Educational Books, Kensington NSW, p 611.

3. OECD Guidelines for Testing of Chemicals, Method 301 E. Modified OECD Screening Test.

4. Hazleton Laboratories America, 1986, *Acute oral toxicity study in rats T-3862*, data on file, Madison, Wisconsin.

5. Riker Laboratories Inc, 1980, *Acute dermal toxicity study with T-2454De in albino rabbits*, data on file, St. Paul, Minosota.

6. Hazleton Laboratories America, 1986*, Primary dermal irritation/corrosion study in rabbits -T-3862*, data on file, Madison, Wisconsin.

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9. Hazleton Laboratories America, 1986*, Dermal sensitisation study of T-3862 in guinea pigs - maximisation test -T-3862*, data on file, Madison, Wisconsin.

10. Magnusson, B & Kligman, A M 1970, *Allergic Contact Dermatitis in the Guinea-pig: Identification of Contact Allergens*, Thomas CC, Springfield, Illinois.

11. Huntingdon Research Center Ltd. (HRC), 1994, *Bacterial mutagenicity assay of T-3862*, data on file, Huntingdon, Cambridgeshire, England.

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13. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(1994)], Australian Government Publishing Service, Canberra.

14. American Society for Testing and Materials. 1980. *Standard practice for conducting basic acute toxicity tests with fish, macroinvertebrates and amphibians*. May, 1980, ASTM Committee E-35.23. page 25.

15. US Environmental Protection Agency. 1985. *Toxic Substances Control Act Test Guidelines; Final Rules, Daphnid Acute Toxicity Test*. Federal Register Vol. 50 (No. 188), September 27, 1985, 797.1300.

16. Standards Australia 1994, *Australian Standard 1336-1994*, *Eye protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney.

17. Standards Australia/Standards New Zealand 1992, *Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, Standards Association of New Zealand Publ, Wellington.

18. Standards Australia 1987, *Australian Standard 2919-1987, Industrial Clothing,* Standards Association of Australian Publ., Sydney.

19. Standards Australia 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding electrical and medical gloves),* Standards Association of Australia Publ., Sydney.

20. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets* [NOHSC:2011(1994)], Australian Government Publishing Service, Canberra.