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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Magenta M-377

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Magenta M-377

1. APPLICANT

Ilford (Australia) Pty Ltd of Cnr Forster and Ferntree Gully Roads MT WAVERLEY VIC 3149 has has submitted a standard notification statement in support of their application for an assessment certificate for Magenta M-377.

2. IDENTITY OF THE CHEMICAL

Magenta M-377 is considered not 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 and spectral data have been exempted from publication in the Full Public Report and the Summary Report.

Chemical Abstracts Service (CAS) Registry No.:	not assigned
Other Names:	sulfonated azo-dye
Trade Name:	Magenta M-377 (product containing < 10% of notified chemical), Dye M-377 (product containing < 10% of notified chemical)
Method of Detection and Determination:	infrared (IR), ultraviolet-visible (UV/Vis) and nuclear magnetic resonance (NMR) spectroscopy

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	garnet powder
Melting Point:	> 306°C
Specific Gravity:	D_4^{20} = 0.486 ± (0.009)
Vapour Pressure:	not determined (see comments below)
Water Solubility:	> 575g.L^{-1} at 30°C

Partition Co-efficient (n-octanol/water):	log P_{ow} = -5.981 (calculated)
Hydrolysis as a Function of pH:	$T_{1/2}$ at pH 4.0 > 1 y^{-1} $T_{1/2}$ at pH 7.0 > 1 y^{-1} $T_{1/2}$ at pH 9.0 > 1 y^{-1}
Adsorption/Desorption:	not determined (see comments below)
Dissociation Constant:	not determined (see comments below)
Flash Point:	not determined
Flammability Limits:	not considered as highly flammable
Autoignition Temperature:	> 420°C
Explosive Properties:	non-explosive
Surface Activity:	72.8mN.m^{-1} at a concentration of 0.25 g.L^{-1} 72.4mN.m^{-1} at a concentration of 0.50 g.L^{-1} 72.6mN.m^{-1} at a concentration of 1.00 g.L^{-1}
Reactivity/Stability:	not considered to be reactive

Comments on Physico-Chemical Properties

Tests were performed according to EEC/OECD test guidelines at facilities complying with OECD Principles of Good Laboratory Practice (1).

As the notified chemical is a trisodium salt of a high molecular weight dye its vapour pressure is expected to be low.

The results of the study on abiotic degradation of the notified chemical indicate that it is stable to hydrolytic decomposition.

No data were provided for the adsorption/desorption behaviour of the notified chemical. Based on the high water solubility and extremely low partition coefficient it is not expected to adsorb strongly to soils or sediment.

The notified chemical contains sulfonic acid groups that would be totally dissociated in water. The notified chemical also contains primary and secondary amines which are expected to have typical basicity.

The notified chemical is not expected to be surface active. By definition, a chemical has surface activity when the surface tension is less than 60 mN.m^{-1} (2).

4. PURITY OF THE CHEMICAL

Degree of Purity: 91.6%

Toxic or Hazardous Impurities: none

Non-hazardous Impurities (> 1% by weight):

Chemical name: dimeric dye
Weight percentage: 3.2%
CAS No.: not available

Chemical name: unidentified dyes
Weight percentage: 5.3%
CAS No.: not available

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will not be manufactured in Australia. It will be imported into Australia at a concentration of less than 10% in prepared inks in either ready to use cartridges (~50 mL) or 100 to 500 mL plastic refill bottles. Import volumes of the notified chemical are expected to be between 100 and 1 000 kg per annum between 1997 and 2000 and beyond.

6. OCCUPATIONAL EXPOSURE

Exposure of transport workers to the notified chemical is unlikley under normal working conditions.

The notified chemical will be used in ink-jet printers Australia wide, for predominantly commercial and industrial uses. The life span of the ready-to-use cartridge is dependent upon the amount of use but generally is for up to 18 months. During this time the cartridges may be refilled on average once every 2 months.

Normal handling, involving replacement of the spent ink cartridge by service technicians or office workers will not result in exposure to the notified chemical as it is contained within the sealed cartridge. Exposure during refill of the cartridges by office workers will vary dependent upon the office printing requirements but as the cartridges are likely to be filled infrequently the potential for exposure is minimal. If accidental exposure occurs it will be intermittent and most likely via the dermal route.

Once printed onto the paper the ink is bound to the paper thus preventing exposure to the notified chemical.

7. PUBLIC EXPOSURE

Infrequent dermal exposure to inks may occur when refilling empty ink cartridges. Public exposure to the notified chemical is possible in the event of an accident during transport and storage, but the likelihood of a substantial spill occurring is low in view of the packaging.

8. ENVIRONMENTAL EXPOSURE

Release

Environmental exposure will result from the disposal of printed paper and discarded cartridges or bottles. In addition to landfill, printed paper may also be recycled after first being subjected to a de-inking process. Waste paper is repulped using a variety of alkalis, dispersing agents, wetting agents, water emulsifiable organic solvents and bleaching agents. These chemicals enhance the fibre separation, ink detachment from the fibres, pulp brightness and the whiteness of the paper. After pulping, the contaminants and the ink are separated from the fibres by pumping the stock through various heat washing, screening, cleaning, flotation and dispersion stages. De-inking wastes are expected to go to trade waste sewers. On combustion water and oxides of carbon, nitrogen and sulphur will be released.

Ink residues contained in the emptied refill bottles and cartridges are expected to remain within these containers.

Fate

The high water solubility of the notified chemical indicates that unbound residues released directly to the aquatic compartment, for example, as a result of de-inking of paper, are likely to remain in solution where they will be rapidly diluted due to low quantities expected.

The substance was examined for biodegradation potential using EEC Directive 92/69, Part C.4-C (Modified Sturm Test), and OECD Test Guideline 301B. Over the 28-day test, biodegradation reached 9%, indicating that Magenta M377 is not readily biodegradable under the conditions of the test.

The bioaccumulation potential of the dye was not investigated. The high molecular weight (~800), extremely low partition coefficient (log Pow = -5.98) and high water solubility (> 575 $g.L^{-1}$) of the notified chemical indicate that significant bioaccumulation is not likely.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Magenta M-377

Test	Species	Outcome	Reference
acute oral toxicity	rat	> 2 000 $mg.kg^{-1}$	(3)
acute dermal toxicity	rat	> 2 000 $mg.kg^{-1}$	(4)
skin irritation	rabbit	slight irritant	(5)
eye irritation	rabbit	slight irritant	(6)
skin sensitisation	guinea pig	non-sensitiser	(7)

9.1.1 Oral Toxicity (3)

Species/strain:	rat/Sprague-Dawley ICO:OFA-SD (IOPS Caw)
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	oral gavage at a concentration of 2 000 $mg.kg^{-1}$ of test material in distilled water
Clinical observations:	none
Mortality:	nil
Morphological findings:	no abnormalities detected
Test method:	OECD test guidelines (1)
LD_{50}*:*	> 2 000 $mg.kg^{-1}$
Result:	the notified chemical was of low acute toxicity in an oral limit test in rats

9.1.2 Dermal Toxicity (4)

Species/strain:	rat/Sprague-Dawley ICO:OFA-SD (IOPS Caw)
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	the notified chemical was applied as a paste in

	distilled water at a dose level of 2 000 $mg.kg^{-1}$ under a semi-occluded dressing for 24 hours after which excess test material was removed by washing the site with distilled water
Clinical observations:	none
Mortality:	nil
Morphological findings:	no abnormalities detected
Test method:	OECD test guidelines (1)
LD_{50}:	> 2 000 $mg.kg^{-1}$
Result:	the notified chemical was of low acute dermal toxicity in a dermal limit test in rats

9.1.3 Inhalation Toxicity

This test was not conducted as it is not considered to be an appropriate route of exposure

9.1.4 Skin Irritation (5)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3/male
Observation period:	13 days
Observations:	moderate to very slight purple colouration of the test site was observed until the end of the study, this obscured the test site and an assessment of erythematous response could not be made; there were no other observations indicative of skin irritation
Method of administration:	500 mg of neat test material moistened with distilled water was applied to the shaved flank of each rabbit and secured by means of a semi-occlusive dressing; the test material was removed after 4 hours
Test method:	OECD test guidelines (1)
Result:	staining of the skin by the notified chemical prevented evaluation of erythema which may

have been present; as no other signs of irritation were observed the notified chemical is considered to be a no more than a slight irritant

9.1.5 Eye Irritation (6)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3/male
Observation period:	3 days
Observations:	very slight or slight conjunctival redness was observed at the 24 hour reading in all animals; conjunctival redness was masked by a garnet colouration of the conjunctiva one hour after treatment, only; no effects on the iris or the cornea were noted; all signs of irritation had regressed by 48 hours; evaluation of the irritant response was made according to Draize (8)
Method of administration:	100 mg of the test material was instilled into the conjunctival sac of the left eye of each rabbit, the right eye serving as controls; the eyes were not irrigated after administration of the test material
Test method:	OECD test guidelines (1)
Result:	the notified chemical was considered to be non-irritant in the rabbit eye

9.1.6 Skin Sensitisation (7)

Species/strain:	guinea pig/Dunkin-Hartley
Number of animals:	20/test and 10/control group
Induction procedure:	Day 1: 3 pairs of intrdermal injections: - 0.1mL Freund's complete adjuvant (FCA):isotonic saline (1:1(v/v)) - 0.1mL of 10% concentration of test material in isotonic saline - 0.1mL of 10% concentration of test material in FCA:isotonic saline (1:1(v/v)

Day 7: test area treated with 0.5mL per injection site of 10% (w/w) sodium lauryl sulfate (10%w/w) in vaseline

Day 8: occluded application of 5% concentration of test material for 48 hours

Challenge procedure:

Day 22: occluded application of 5% concentration of test material for 24 hours

Day 33: occluded application of 5% concentration of test material for 24 hours

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
5%	0/20**	0/20	0/10	0/10

* time after patch removal
** number of animals exhibiting positive response

Re-challenge outcome:

	Test animals		***Control animals***	
Re-challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
5%	0/20**	0/20	0/10	0/10

* time after patch removal
** number of animals exhibiting positive response

Test method: OECD test guidelines (1)

Observations: no cutaneous reactions were observed after both challenge applications; a red colouration of the test site which could mask very slight or well defined erythema was noted in all animals after the first challenge

Result: the notified chemical was not a skin sensitiser in guinea pigs

9.2 Repeated Dose Toxicity (9)

Species/strain: rat/Sprague-Dawley

Number/sex of animals:	5/sex in low and mid dose groups, 10/sex in vehicle control and high dose group
Method of administration:	the notified chemical was administered orally by gavage
Dose/Study duration::	the notified chemical was administered daily for a period of 28 days: control: vehicle only (purified water) low dose: 150 $mg.kg^{-1}$ mid dose: 450 $mg.kg^{-1}$ high dose: 1 350$mg.kg^{-1}$ on completion of the treatment period , five animals/sex in the control and high dose group were kept on study for a 2 week reversibility period
Clinical observations:	no signs of systemic toxicity were observed; during the dosing period the faeces and urine were coloured pink in all animals in all treated groups, the extremities and and tails were coloured pink in most animals in the high dose group, colouration was considerd to be related to the elimination of the test material or its metabolites; body weight gain and food consumption were similar in control and treated animals during the study
Clinical chemistry/Haematology	no treatment related effects were observed
Organ weights:	higher absolute and relative adrenal weight was noted at the end of the treatment period in males in the mid and high dose group and at the end of the reversibility period in animals in the high dose group
Histopathology:	slight to moderate cortical cell hypertrophy in the *zona fasciculata* and the *zona reticularis* of the adrenal glands was noted in all animals in the high dose group after the treatment period; this finding was noted with lower incidence and severity in the recovery group
Test method:	OECD test guidelines (1)
Result:	administration of doses up to 450 $mg.kg^{-1}$ daily for 28 days induced an increase of adrenal weights, no other changes of toxicological

significance were observed; repeated doses of 1 350 $mg.kg^{-1}$ daily over the same time period resulted in higher adrenal weights which correlated with cortical cell hypertorphy

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (10)

Strains:	TA 98, TA 100, TA 102, TA 1535 and TA 1537
Concentration range:	125, 250, 500, 1 000, 2 000 µg/plate; assays were carried out in the presence or absence of S9 mix
Test method:	according to OECD test guidelines (1)
Result:	the notified chemical was found not to be mutagenic in the bacterial strains tested under the conditions of the assay

9.3.2 Salmonella typhimurium Reverse Mutation Assay (11)

Strains:	TA 98, TA 100, TA 1535, TA 1537 and *Escherichia coli* WP*uvr*A
Concentration range:	30, 100, 300,1 000, 3 000 µg/plate; assays were carried out in the presence or absence of S9 mix
Test method:	according to OECD test guidelines (1)
Result:	the notified chemical was found not to be mutagenic in the bacterial strains tested under the conditions of the assay

9.3.3 Chromosome Aberration Assay in Human Lymphocytes (12)

Experiment 1

Concentration range:	for treatment: 30, 100, 300, 1 000, 3 000 and 5 000 $\mu g.mL^{-1}$ (with or without S9 mix) for chromosomal aberration scoring 1 000, 3 000 and 1 000 $\mu g.mL^{-1}$ (with or without S9 mix); cells were incubated for 48 hours and

	then harvested 20 hours after the beginning of treatment
Test method:	OECD test guidelines (1)
Result:	the notified chemical was not considered to be clastogenic when tested in cultured human lymphocytes under the conditions of this assay

Experiment 2

Concentration range:	for treatment: 300, 1 000, 3 000 and 5 000 $\mu g.mL^{-1}$ (without S9 mix, for all harvest times) for chromosomal aberration scoring: 1 000, 3 000 and 1 000 $\mu g/mL$ (with or without S9 mix, for the 20 hour harvest time), 5 000 $\mu g.mL^{-1}$ (with or without S9 for the 48 hour harvest time); as indicated above cells were incubated for 48 hours and then harvested 20 hours and 44 hours after the beginning of treatment
Test method:	OECD test guidelines (1)
Result:	the notified chemical was not considered to be clastogenic when tested in cultured human lymphocytes under the conditions of this assay

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse

This study was not conducted by the notifier on the basis that negative responses were obtained in 2 other genotoxicity assays. This was considered to be acceptable.

9.4 Overall Assessment of Toxicological Data

The notified chemical was found to be of low acute toxicity in rats when administered by the oral and dermal routes (LD_{50} > 2 000 $mg.kg^{-1}$ in both studies). The notified chemical was a slight eye irritant when tested in rabbits and considered likely to be a slight skin irritant in rabbits. The results of a guinea pig maximisation test indicate that the chemical is not a skin sensitiser.

Findings in a 28-day repeat dose oral toxicity study indicate the adrenal gland as the target organ for toxicity at high dose levels.

The notified chemical was not mutagenic in bacteria in the presence or absence of metabolic activation, and it was not clastogenic when tested *in vitro* in human lymphocytes.

Based on the results of the toxicity studies summarised above, the notified chemical would not be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (13).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Ecotoxicological data is not required for chemicals with import volumes less than one tonne per year according to the Act. However, the following ecotoxicity studies have been supplied by the notifier. The tests were carried out to OECD Test Methods (1).

Test	Species	Results
Acute Toxicity (96 h, static) (OECD Guideline 203)	Rainbow trout Oncorhynchus mykiss	NOEC $\geq$ 100 $mg.L^{-1}$
Acute Toxicity (48 h, static) (OECD Guideline 202)	Daphnia magna	NOEC $\geq$ 100 $mg.L^{-1}$
Growth Inhibition (72 h) (OECD Guideline 201)	Algae Scenedesmus subspicatus	NOEC $\geq$ 100 $mg.L^{-1}$

* NOEC - no observable effect concentration

Limit tests were conducted for all test organisms. Some fish were observed swimming calmly towards the bottom of the tank in the fish acute toxicity test. No unusual observations were made during the duration of the ecotoxicity studies on *Daphnia* and algae.

The ecotoxicity data for the notified chemical indicate that Magenta M-377 can be considered practically non-toxic to fish, *Daphnia* and algae.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Magenta M-377 is not expected to present a hazard to the environment. During normal use the chemical will be bound to the treated substrate.

The residues of uncured inks from discarded colour cartridges are expected to remain in the cartridge housing. Losses generated in the refilling process are expected to be low.

Recycling of treated paper could result in the release of a proportion of the notified

chemical to the aquatic compartment where it will be rapidly diluted to environmentally negligible levels. Where recycling does not occur, the notified chemical will be widely distributed in landfills around Australia where the notified chemical is expected to remain bound to the treated paper. In the event of leaching the environmental effects are expected to be negligible due to the low toxicity and low bioaccumulation potential of the notified chemical.

Spills of the dye should not present an environmental hazard when cleaned up according to the Material Safety Data Sheets (MSDS).

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The occupational health risk associated with importation, storage, use or disposal of the notified chemical is expected to be minimal.

The toxicological profile of Magenta M-377 suggests that it is unlikely to be acutely toxic via the oral and dermal routes and is likely to be neither mutagenic nor clastogenic. However, it may cause slight skin and eye irritation. It was not a skin sensitiser and it is unlikely to exhibit significant toxic effects on repeated or prolonged exposure.

The notified chemical will be used in ink-jet reprographic processes and will be imported in sealed ink-jet cartridges which are inserted directly into ink-jet printers for commercial and industrial use. Exposure to the notified chemical during normal handling is not expected other than in the unlikely event that the cartridge is faulty and ruptures. Refill bottles containing the ink will also be imported and may be used every 2 months during the life of the cartridge (18 months). During refill there is minimal potential for occupational exposure as the cartridges will be filled infrequently and the notified chemical is present in the ink at low percentages (<10%).

The notified chemical has low dermal toxicity in rats but caused slight skin irritation in rabbits. Considering the low concentration (<10%) in consumer products, infrequent, minor dermal exposure from refilling ink cartridges is unlikely to pose a health hazard to the public.

Based on the information provided and the intended use, the notified chemical does not appear to pose a significant hazard to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to Magenta M-377 the following guidelines and precautions should be observed:

- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly with absorbents which should then 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* (14).

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

1. Organisation for Economic Co-operation and Development 1995-1996, *OECD Guidelines for the Testing of Chemicals on CD-Rom*, OECD, Paris.

2. European Economic Community (EEC), E.D. December 1992, *A.5 Surface Tension Methods for the determination of physico-chemical properies*, vol. EEC Publication No. L383.

3. de Jouffrey, S. 1995, *Acute Oral Study in Rats*, Project no., CIT/Study No. 12988 TAR/M-377/Ilford, C.I.T., Evreux.

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5. de Jouffrey, S. 1995, *Skin Irritation Study in Rabbit*, Project no., CIT/Study No. 12990 TAL/M-377/Ilford, C.I.T., Evereux, France.

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8. Draize, J.H. 1959, 'Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics', *Association of Food and Drug Officials of the US*, vol. 49, pp. 2-56.

9. Fabreguettes, C. 1996, *4-Week Toxicity Study by Oral Administration (Gavage) in Rats Followed by a 2-Week Reversibility Period*, Project no., CIT/Study No. 13709 TSR/M-377/Ilford, C.I.T., Evreux.

10. Molinier, B. 1995, *Bacterial Reverse Mutation Test*, Project no., CIT/Study No. 12994 MMO/M-377/Ilford, C.I.T., Evreux.

11. de Jouffrey, S. 1996, *Bacterial Reverse Mutation Test*, Project no., CIT/Study No. 13859 MMJ/M-377/Ilford, C.I.T., Evreux.

12. de Jouffrey, S. 1996, *In Vitro Mammalian Chromosome AberrationTest in Cultured Lymphocytes*, Project no., CIT/Study No. 13694 MLH/M-377/Ilford, C.I.T., Evreux.

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

14. 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.

Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe