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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION

AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

AROMATIC DIGLYCIDYL ETHER

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

AROMATIC DIGLYCIDYL ETHER

1. APPLICANT

3M Australia Pty Limited of 2-74 Dunheved Circuit ST MARYS NSW 2760 has submitted a standard notification statement in support of their application for an assessment certificate for aromatic diglycidyl ether.

2. IDENTITY OF THE CHEMICAL

Aromatic diglycidy ether 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 exact import volume have been exempted from publication in the Full Public Report and the Summary Report.

Trade Name:	3M PR500 Molding Resin (imported resin containing 10 - 30% of the notified chemical - see Material Safety Data Sheet (MSDS))
Method of Detection and Determination:	ultraviolet/visible, infrared and nuclear magnetic resonance spectroscopy; high performance liquid chromatography with ultraviolet or infrared detection

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3kPa:	white/cream to tan coloured solid.
Melting Point:	71-87°C (at 101.3kPa)
Boiling Point:	> 300°C
Density:	1 230 kg/m^3 at 20°C
Vapour Pressure:	< 2.5 x 10^{-2} Pa at 25°C (estimate)
Water Solubility:	< 0.01mg/L at room temperature and pH 5, 7 or 9.

Partition Coefficient (n-octanol/water):	log P_{ow} = 4.65 at room temperature.
Hydrolysis as a Function of pH:	not determined due to low water solubility
Adsorption/Desorption:	not determined due to low water solubility
Dissociation Constant:	not determined due to low water solubility
Flash Point:	not determined
Flammability Limits:	not flammable
Autoignition Temperature:	does not autoignite
Explosive Properties:	not explosive
Particle Size:	> 1 mm
Reactivity/Stability:	not reactive
Fat Solubility:	4 042 mg/100g solvent at 37°C.

Comments on Physico-Chemical Properties

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

Because of the limited water solubility of the substance, the column elution method was used to test solubility. Testing was performed at three different pH values, with results confirming solubility of < 0.1 mg/L at all values.

Hydrolysis testing was not conducted, which is acceptable due to the very low water solubility of the notified chemical (with solubility being tested at pH 5, 7, 9). There are epoxide functionalities on the notified chemical which may hydrolyse within the environmental pH range, but would be precluded by low solubility.

Adsorption/desorption data were not provided. The high partition co-efficient and very low water solubility suggest the notified chemical will strongly adsorb to organic matter in soils and sediments.

No dissociation constant was provided for the chemical which does not contain any readily dissociable moieties.

4. PURITY OF THE CHEMICAL

Degree of Purity: 85-90%

Toxic or Hazardous impurities: none known

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

Chemical name: high molecular weight oligomers of the notified substance

CAS No.: none

Weight percentage: 5 - 15%

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical is to be used as a component of an epoxy resin formulation for composite materials for use in the aerospace industry. It is imported in a formulation at a level of between 10 and 30% (see attached MSDS for 3M PR500 Molding Resin), at a rate of up to 10 tonnes per annum for the first 5 years.

6. OCCUPATIONAL EXPOSURE

The notified substance will be imported as part of an epoxy product which will be used to produce composite materials for the aerospace industry. The product is imported in sturdy 20 litre pails. The pails are warmed in water in a sealed heating vessel to liquify the contents which are then pumped out directly into moulds containing carbon fibres. The moulds are heated to approximately 180°C for curing and release of vapours during curing is stated not to occur.

Worker contact with the product containing the notified substance is expected to be minimal. The most likely route of exposure is via the skin.

7. PUBLIC EXPOSURE

There is negligible potential for public exposure to the notified chemical arising from its proposed use within the aerospace industry.

8. ENVIRONMENTAL EXPOSURE

Release

At the end users site, the imported product is loaded into a heating vessel (100 - 200 L) where it is heated until it forms a liquid. This is pumped from the vessel into a mould containing carbon fibres. The mould is heated to a temperature which enables polymerisation, and left to cure. The heating vessel is sealed, and the heated mould has a purge pipe which vents into the outside air.

The dispensing system used is dedicated, and pumplines are purged with air in order to get maximum resin into the moulds. As such, residues from pumplines will be minimal, with the notifier indicating around 0.2% (10 kg per annum).

Any residues remaining in the pails are polymerised and landfilled prior to the pails being returned to the notifier for reuse.

Fate

The notified substance was examined for biodegradation potential according to EEC Directive 84/449/EEC, a Closed-bottle test and Sturm test were employed. The two tests of biodegradation gave differing results. Results from the Closed-bottle test indicated a partial degradation of the notified substance (~55%) after 28 days. In contrast, the Sturm test indicated only a 3-4% degradation after 28 days. The closed-bottle test employed a solvent vehicle (acetone) to introduce the test substance into the medium. It is possible that evaporation of the solvent was not complete before the test sample was introduced into the inoculated medium and hence confounded the results. It is concluded that the notified substance, based on the Sturm test, is not readily biodegradable. In a separate microbial inhibition test the notified substance was shown to be non-inhibitory toward the bacterium *Pseudomonas fluorescens*.

The bioaccumulation potential of the notified substance was not determined. The high partition coefficient and fat solubility and low water solubility of the substance indicate that it may have the ability to bioaccumulate.

Adsorption and desorption from soils was not investigated due to the low water solubility of the compound, however leaching of the chemical from landfills is not expected to occur as the chemical will be inextricably bound in the matrix of a resin.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the Acute Toxicity of aromatic diglycidyl ether

TEST	SPECIES	RESULT	REFERENCE
Acute Oral Toxicity	Rat	LD_{50} > 5 000 mg/kg	(1)
Acute Oral Toxicity	Rat	LD_{50} > 5 000 mg/kg	(2)
Acute Dermal Toxicity	Rat	LD_{50} > 2 000 mg/kg	(2)
Skin Irritation	Rabbit	Non-irritating	(2)
Skin Irritation	Rabbit	Non-irritating	(3)
Eye Irritation	Rabbit	Slight irritant	(2)
Eye Irritation	Rabbit	Slight irritant	(4)
Skin Sensitisation	Guinea Pig	Non-sensitiser	(2)
Skin Sensitisation	Guinea Pig	Non-sensitiser	(5)

9.1.1 Oral Toxicity (1)

(A)	*Species/Strain:*	rat/Sprague-Dawley
	Number/Sex of Animals:	5 males, 5 females
	Observation Period:	14 days
	Method of Administration:	gavage with corn oil as vehicle
	Clinical Observations:	no significant observations
	Mortality:	none
	Pathology:	no significant findings.
	Test Method:	OECD Guidelines (6)
	LD_{50}::	> 5 000 mg/kg
	Result:	the notified substance exhibits low acute oral toxicity in rats

Oral Toxicity (2)

(B)	*Species/Strain:*	rat/Fischer 344
	Number/Sex of Animals:	5 males, 5 females

Observation Period:	14 days
Method of Administration:	gavage with water/carboxymethyl cellulose vehicle
Clinical Observations:	no significant observations
Mortality:	none
Pathology:	none noted
Test Method:	directive 67/548/EEC (Annex V 84/449/EEC) 1984 (7)
LD_{50}:	> 5 000 mg/kg
Result:	the notified substance exhibits low acute oral toxicity in rats

9.1.2 Dermal Toxicity (2)

Species/Strain:	rat/Sprague-Dawley
Number/Sex of Animals:	5 males, 5 females
Observation Period:	14 days
Method of Administration:	a wetted powder in water applied under gauze patch to shaved skin for 24 hours.
Clinical Observations:	no significant observations
Mortality:	1 female on day 3 (sacrificed) due to traumatic injury unrelated to test compound administration.
Pathology:	none noted
Test Method:	Directive 67/548/EEC (Annex V 84/449/EEC) 1984 (7)
LD_{50}:	> 2 000 mg/kg
Result:	the notified substance exhibits low acute dermal toxicity in rats

9.1.3 Skin Irritation (2)

(A)	*Species/Strain:*	rabbit/New Zealand White

	Number/Sex of Animals:	3 males, 3 females
	Observation Period:	7 days
	Method of Administration:	five hundred milligrams of test substance moistened with water under a semi-occlusive gauze held in place for 4 hours.
	Test Method:	OECD Guidelines (6)
	Result:	no erythema or oedema was observed in any animal at any time point; the notified chemical was not a skin irritant in rabbits

Skin Irritation (3)

(B)	*Species/Strain:*	rabbit/New Zealand White
	Number/Sex of Animals:	1 male, 2 females
	Observation Period:	3 days
	Method of Administration:	five hundred milligrams of test substance moistened with saline under a semi occlusive gauze held in place for 4 hours.
	Test Method:	OECD Guidelines (6)
	Result:	no erythema or oedema was observed in any animal at any time point; the notified chemical was not a skin irritant in rabbits

9.1.5 Eye Irritation (2)

(A)	*Species/Strain:*	rabbit/New Zealand White
	Number/Sex of Animals:	3 males, 3 females
	Observation Period:	7 days
	Method of Administration:	seventy milligrams of test substance into conjunctival sac of one eye of each rabbit.
	Test Method:	OECD Guidelines (6)
	Result:	a slight redness was noted in all treated eyes at 1 and 4 hours post treatment; this effect had subsided in all but 2 rabbits by 24 hours; the

chemical is minimally irritating to the rabbit eye

Eye Irritation (4)

(B) *Species/Strain:* rabbit/New Zealand White

Number/Sex of Animals: 3 females

Observation Period: 3 days

Method of Administration: sixty milligrams of test substance into conjunctival sac of one eye of each rabbit.

Test Method: OECD Guidelines (6)

Result: diffuse reddening of the conjunctivae and injection of the iris were observed in all treated animals at 1 hour; these effects had substantially subsided at 24 hours; the notified chemical is minimally irritating to the rabbit eye

9.1.6 Skin Sensitisation (2)

(A) *Species/Strain:* guinea Pig/Dunkin Hartley

Number of Animals: 10/sex-test, 5/sex-control

Induction Procedure: animals were induced with a 60% concentration of the notified substance in Vaseline; the test material was applied to the shaved flank of each animal for 24 hours under a patch held in place by elastic tape; this procedure was done one day a week for three weeks.

Challenge Procedure: fourteen days after the last induction dose, animals were topically challenged with a 60% dose in Vaseline on opposite flank; the challenge dose was applied under occlusive dressing for 24 hours.

Challenge Outcome: the test material did not induce any erythema or oedema in any treated animal.

	Test Method:	Buehler Test (8)
		Result: the notified chemical was not a skin sensitiser in guinea pigs
	Skin Sensitisation (5)	
(B)	*Species/Strain:*	guinea Pig/Dunkin Hartley
	Number of Animals:	5/sex-test and control
		Induction Procedure: animals were induced with a 100% concentration of the notified substance in diethyl-ether with saline; the test material was applied to the shaved dorsal region of each animal for 24 hours under an occlusive patch; this procedure was conducted once a week for three weeks.
		Challenge Procedure: fourteen days after the last induction dose, animals were topically challenged with a 100% concentration on a previously untreated area; the challenge dose was applied under an occlusive dressing for 24 hours
		Challenge Outcome: no differences were observed between the negative control group and the test group.
	Test Method:	Buehler Test (8)
		Result: the notified chemical was not a skin sensitiser in guinea pigs

9.2 Repeated Dose Toxicity (9)

Species/Strain:	rabbit/New Zealand White
Number/Sex of Animals:	5 males/5 females per dose group
Method of Administration:	dermal application

Dose/Study Duration:	0, 200, 500, 1 000 or 2 000 mg/kg per day for 14 days (6 hrs/day)
	Clinical Observation: dermatitis on or around site of application. no other significant effects noted
	Clinical Chemistry/Haematology: no toxicologically significant observations related to administration of the test material were noted
	Histopathology: no toxicologically significant observations related to administration of the test material were noted
Test Method:	in-house protocol (9)
	Result: no systemic toxicity was observed; local toxicity was observed and confined to the site of application

9.3 GENOTOXICITY

9.3.1 (A) Induction of Point Mutations/Recombinogenic Potential (10)

Species/Strain:	*Salmonella typhimurium* TA 1535, TA 1537, TA 1538, TA 98, TA 100; *Saccharomyces cerevisiae* D3.
	Concentration Range: point mutation assay 10 - 5 000 μg/plate; recombinogenicity assay 0.01 - 1.0%; both ±S9
	Test Method: point mutations, Ames et al (11), McCann et al (12); Recombinogenicity, Zimmerman et al (13)
	Result: The notified substance did not induce reverse mutation in *S.typhimurium* or mitotic recombination in *S.cerevisiae*; positive and negative controls gave appropriate results in both studies.

(B) Induction of Point Mutations (14)

Species/Strain: *Salmonella typhimurium* TA 1535, TA 1537, TA 1538, TA 98, TA 100; *Escherichia coli* WP2 *uvrA* pKM101

Concentration Range: Both studies, 31.25 - 5,000 μg/plate; both ± S9.

Test Method: *S. typhimurium* Ames et al (11) McCann *et al*. (12); *E. coli*, Venitt and Crofton-Sleigh (15)

Result: the notified chemical did not induce reverse mutation in either *S. typhimurium* or *E. coli*; positive and negative controls gave appropriate results.

9.3.2 In Vitro Chromosomal Aberrations in Chinese Hamster Ovary Cells (16)

Doses: 10 - 100 μg/ml in the absence of S9 and 2-20 μg/mL in the presence of S9

Duration: in the presence of S9 cells were incubated for 3 hours and sampled 8, 12 and 24 hours post-initiation; in the absence of S9, cells were incubated for 24 hours and sampled at the same time point (24 hours)

Test Method: US EPA Guidelines (17)

Result: the notified chemical was not considered clastogenic in chinese hamster ovary cells

9.4 OVERALL ASSESSMENT OF TOXICOLOGICAL DATA

The notified substance exhibited low acute oral and dermal toxicity in rats (oral LD_{50} > 5 000 mg/kg; dermal LD_{50} > 2 000 mg/kg). It was non-irritating to rabbit skin but caused slight irritation in the rabbit eye. The notified substance did not cause skin sensitisation in guinea pigs. In a 14-day repeated dose dermal study, no systemic toxicity was observed. The only effect noted was dermatitis which occurred at the site of application from about day 6.

The notified chemical was not genotoxic toward *Salmonella typhimurium*, *Escherichia coli* or *Saccharomyces cerevisiae*, and was not clastogenic in chinese hamster ovary cells *in vitro*.

The notified substance would not be classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (18) for acute lethal effects, irritancy, sensitising effects, severe effects after repeated or prolonged exposure, or mutagenicity.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were carried out to OECD Test Methods.

TEST	SPECIES	RESULT
Acute toxicity (F; M)*	Rainbow trout	LC_{50} > 2.2 μg/L; NOEC** > 2.2 μg/L (19)
Immobilisation (S; M)*	*Daphia magna*	LC_{50} > 7.0 μg/L; NOEC > 7.0 μg/L (19)
Algal growth inhibition (S; M)*	*Selenastrum capricornutum*	EC_{50} > 3.8 μg/L; NOEC (AUC) 0.84 μg/L NOEC (SGR) < 0.38 μg/L (19)
Inhibition of Bacterial growth (Leachate test)	*Pseudomonas fluorescens*	No significant inhibition (20)

* No-observable effect concentration. F=Flow through; S=Static; M=Measured Concentration

Test media containing the notified chemical were generated by recirculating dilution water/culture medium through glass (Rainbow trout), or stainless steel (*Daphnia magna* and algae) columns packed with inert particulate material coated with 5-10% of the notified chemical. The organisms were then exposed to the resulting test media when the results of chemical analysis showed the concentrations of the principal component of the notified chemical to have stabilised.

The results show the chemical to be non toxic to fish and *Daphnia*, up to its limit of solubility (2.2 µg/L for fish; 7.0 µg/L for *Daphnia magna*). No deaths or sub lethal effects were observed during the fish testing, and none of the *Daphnia* were immobilised during 48 h exposure.

While an EC_{50} for algal growth inhibition could not be determined due to the limited solubility (EC_{50} > 3.8 µg/L), an inhibitory effect of average specific growth rates were observed at the lowest concentration tested of 0.38 µg/L.

In the microbial inhibition study, a water-leachate of 100 mg notified substance/100 mL inhibition medium inhibited microbial growth by 5% after 21 days.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified chemical will be manufactured into moulded composites at one site only in Australia. The moulded articles are typically used in the aerospace industry, and once moulded, the notified chemical is unlikely to present an environmental hazard.

Prior to manufacture, the chemical is transported by road from Sydney to Melbourne. The imported product (containing the notified chemical at 20% w/w) is highly viscous, described in the submission as a paste. As such, any accidental spillage should be easily contained, and should not present a hazard. In light of ability of the notified chemical to inhibit algal growth (NOEC < 0.38 µg/L (ppb), all precautions should be taken to avoid it entering waterways. No instruction of this nature appears on the MSDS.

Around 0.2% of the notified chemical is expected to be lost per annum (10 kg) through residues from pumping lines during manufacture of moulded articles. As a worst case, if this were to enter the sewage (assuming manufacture occurs on 260 days of the year and a daily output to sewer of 250 ML), the concentration in the sewage treatment plant (STP) will be around 0.15 ppb. The low water solubility and high partition coefficient suggest the majority of this will be lost to sludge within the STP and landfilled or incinerated, and minimal amounts only would be expected to enter receiving waters where it would be diluted even further. Although the amounts reaching the aquatic systems based on these figures are likely to provide a sufficient safety margin, the strong ability of the notified chemical to inhibit algal growth makes any release to sewer undesirable. The preferred method of disposal is polymerisation followed by landfill.

While the chemical could bioaccumulate in theory, this is expected to be minimal due to very low exposure of the aquatic compartment.

When used in the manner outlined in the submission, the use of the notified chemical is expected to have a low potential for environmental hazard.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

From the complete set of toxicological data supplied as part of this standard notification, the only hazard identified is the potential for slight eye irritation. Nevertheless the level of irritation seen in rabbits was not sufficient to classify the notified chemical as hazardous according to the Approved Criteria (18).

Exposure of transport and warehouse workers is unlikely as the imported product is contained in sturdy 20 L pails. Exposure of workers during subsequent operations is also expected to be low given that the system for liquifying the imported resin and pumping it into moulds is enclosed and fumes are stated not to be produced during curing.

It can be concluded that the occupational health risk from transport, storage, use and disposal of the notified chemical is low.

The imported product containing the notified chemical is classified as hazardous according to the approved criteria (see MSDS). One of the epoxy resin components (CAS No. 1675-54-3) is a skin sensitiser and an irritant (21) and is present at a concentration of at least 15% which is above the threshold for classification of the resin as hazardous (1% for sensitising effects). Therefore, there is an occupational health risk of skin sensitisation and skin irritation which needs to be minimised by the wearing of personal protective equipment as described below. The risk to the public of skin sensitisation or irritancy is expected to be minimal give the limited opportunity for public exposure.

13. RECOMMENDATIONS

To minimise exposure to the notified chemical the following guidelines and precautions should be observed:

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

When handling the resin to be imported (see attached MSDS) exposure should be minimised by:

- Wearing gloves which conform to Australian Standard (AS) 2161 (22);
- Wearing industrial clothing which conforms to AS 2919 (23);
- Curing drum residues prior to disposal

To limit environmental exposure, the chemical should not be allowed to enter drains or waterways and the statement “Do not allow the chemical to enter drains or waterways” should be added to the MSDS under section 7.

14. MATERIAL SAFETY DATA SHEET

The MSDS for a formulation containing the notified substance was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (24).

The MSDS was provided by the applicant as part of the notification statement. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

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

16. REFERENCES

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3. Glaza, S.M. 1988, *Primary Dermal Irritation in Rabbits with T-4126*, Study No. 71205143, Hazleton Laboratories America, Inc. Madison Wisconsin, USA.

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5. Murchison, T. 1986, *Guinea Pig Skin Sensitisation of Aromatic Diglycidyl Ether*[2]*,* Project No. DRC 2702, Dawson Research Corporation, Orlando Florida USA.

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7. European Economic Community 1984, Annex V (EEC Directive 84/449) to Directive 67/548/EEC. Test Methods for the Determination of Physicochemical, Toxicological and Ecotoxicological Properties listed in Annexes VII and VIII to Directive 79/831. Official Journal of the European Communities L251, vol. 27, 19 September, 1984.

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10. Riccio, E. 1988, *In Vitro Microbiological Mutagenicity Assays of 3M Company's Compound T-4126*, SRI International Menlo Park, California, USA.

[1] the designation for the notified chemical used in the title of the original report has been replaced by the generic name "aromatic diglycidyl ether"

[2] the designation for the notified chemical used in the title of the original report has been replaced by the generic name "aromatic diglycidyl ether"

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12. Mccann, J. *et. al* 1975, “Detection of Carcinogens as Mutagens: Bacterial Tester Strains with R factor Plasmids”, *Proc. Natl. Academy of Science, USA*, vol. 72, pp. 979-983.

13. Zimmerman, F. and Schwaier, R. 1967, “Induction of Mitotic Gene Conversion with Nitrous Acid, 1-methyl-3-nitro-1-nitrosoguanidine and other alkylating agents in *Saccharomyces cerevisiae”, Mol. Gen. Genet*., vol. 100 pp. 63-76.

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15. Venitt, S. and Crofton-Sleigh, C., 1981, “Mutagenicity of 42 coded Compounds in a bacterial assay using *Escherichia coli* and *Salmonella typhimurium*”, In *Evaluation of Short-Term Tests for Carcinogens: Report of the International Program*, Chapter 32, pp 351-360, Edited by I. J. de Serres and J. Ashby Elsevier, New York, USA.

16. Brooks, T. and Wiggins, D. 1990, *Genotoxicity studies with Aromatic Diglycidyl Ether[3]: In Vitro chromosome studies*, Experiment No. 4217, Sittingbourne Research Centre, Kent, England.

17. US EPA 1982, *Pesticide Assessment Guidelines,* US Environmental Protection Agency, Office of Pesticide Programs, Washington DC, USA.

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

19. Girling, A. And Cheesman, H. 1990, *Aromatic Diglycidyl Ether[3]: Acute toxicity to Salmo gairdereri, Daphnia magna and Selenastrum capricornutum*, Experiment No. 4218, Sittingbourne Research Centre, Kent, England.

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[3] the designation for the notified chemical used in the title of the original report has been replaced by the generic name “aromatic diglycidyl ether”

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24. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)],* AGPS, Canberra.