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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

PRIMID XL-552

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

PRIMID XL-552

1. APPLICANT

Evode Powder Coatings Pty. Ltd., Unit 1, 3 Jindalee Place, Riverwood, NSW 2210.

2. IDENTITY OF THE CHEMICAL

Trade Name: PRIMID XL-552

Other Names: CDH 2261, QM-552

Based on the nature of the chemical and the data provided PRIMID XL-552 is considered non-hazardous. Therefore the following have been exempted from publication: Chemical Name; Cas Number; Molecular Formula; Structural Formula; Spectral Data and Molecular Weight.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20^{O}C and 101.3 kPa:	White cystalline solid
Odour	amine-like
Melting Point:	120-124.5 ^{O}C
Relative density:	1.19
Vapour Pressure:	<1 x 10^{-8} kPa at 25^{O}C
Water solubility:	608.3 g/L at 20^{O}C
Fat solubility:	<0.0868 mg/100ml solvent at 37^{O}C

Partition coefficient: (n-octanol/water) log P_{OW} = -2.50 at 21^{O}C

Adsorption-desorption: not provided, on the grounds that the chemical is highly water soluble. The low partition coefficient also suggests that adsorption will be low.

Dissociation constant: not provided, on the grounds that the compound is not expected to dissociate. PRIMID XL-552 does not appear to have any dissociable groups.

Hydrolysis:
at pH4 and 25^{O}C: <10% over 5 days
half life > 1 yr .
at pH7 and 25^{O}C: 10% over 5 days
half life approx 1 yr.
at pH9 and 25^{O}C: 20% over 5 days
half life < 1 yr

Flash point: 104^{O}C

Flammability: nonflammable

Autoignition temperature: does not ignite

Reactivity: PRIMID XL-552 is considered thermostable. May react with strong oxidising agents

Particle size: >75µm

4. PURITY OF THE CHEMICAL

Degree of Purity Typical Purity 87% (82-92%)

Hazardous Impurities Diethanolanime 1.8-2.8%
(2, 2' iminodiethanol)

CAS No	111-42-2
LD_{50} Oral rat	710 mg/kg
LD_{50} Dermal rabbit	12200 mg/kg
skin irritation	mild (1)
eye irritant	severe (1)

sensitisation	reported as sensitiser in humans (2)
other	neurotoxicity, liver and kidney damage has been reported in animals (2, 3)
Exposure standard	13 mg/m^3 (4)
carcinogenicity	on test US NTP

Non Hazardous Impurities

Impurity 1	ester dimer impurity 4.0-8.0% $C_{14}H_{45}O_{10}N_3$ Hexanoic acid, 6-{bis(2-hydroxyethyl) amino}-6-oxo-,2-{ [6- [bis 2-hydroxyethyl) amino]-1,6-dioxohexyl}(2-hydroxyethyl) amino] ethyl ester
Impurity 2	amide trimer impurity 2.0-4.0% ($C_{32}H_{56}O_{14}N_{14}$)
Impurity 3	half acid-half amide impurity 1.0-4.0% $C_{10}H_{19}O_5N$

5. INDUSTRIAL USE

primid xl-552 is used as a crosslinking curing agent in powder coatings for metal products for industrial and domestic use. The company estimates that 4,000 tons of powder coatings containing PRIMID XL-552 will be used annually. The chemical will be imported in quantities of 10-100 tonnes per annum during the first 5 years for formulation into powder coatings. Primid XL-552 will not be manufactured in Australia.

6 OCCUPATIONAL EXPOSURE

Production of powder coatings

PRIMID XL-552, in the form of solid flakes, is combined with various materials used to produce the powder coating, in an

extruder hopper to form a solid resin which is first chipped then micronised into a very fine powder.

The process will therefore involve preparation and mixing of raw materials, extrusion of mixed materials, micronising of extruded materials, quality assurance testing, research and development and supervision of early production trials.

Approximately 50 plant operators producing powder coatings are expected to be exposed Australia wide. Small numbers of staff will be involved in quality assurance and research and development activity.

Plant operators may be exposed to the powder by the dermal route and by inhalation as work is to be carried out with the powder in an open system. Particles of PRIMID XL-552 are >75µm compared to the 7µm upper limit of respirable size (4).

Prevention of Worker Exposure

Exposure is minimised through the use of a particle extraction system and through the use of appropriate personal protective equipment. Standard operating procedures appropriate to each process have been instituted to ensure that correct procedures are followed. A monitoring system is installed to insure that the baghousing is cleaned. After production, the powder is stored in plastic lined fibreboard boxes sealed to prevent exposure.

Applying powder coatings

Powder coating application facilities should have efficient cyclone or baghouse recovery systems.

Education and Training

The material safety data sheet is to be reviewed with employees handling the material before introduction of the new chemical into the workplace. Standard operating procedures are in place for all processes in the production of powder coatings and associated tasks.

To date experience with PRIMID XL-522 has been relatively limited. No evidence of injuries or disease has been reported.

7. PUBLIC EXPOSURE

The potential for public exposure to PRIMID XL-552 is low. The compound is a crystalline solid with a low vapour pressure and is transported in sealed containers. In its use as a crosslinking curing agent in powder coating applications, PRIMID XL-552 is inescapably bound within a high molecular weight, water insoluble polymer matrix. No adverse effects have been reported from Europe or the US, where the product has been in use commercially for 1 and 2 years, respectively.

PRIMID XL-552 is not manufactured in Australia. The product is transported in sealed containers, however no information on the amounts to be transported or the mode of transportation have been provided.

8. Environmental exposure

PRIMID XL-552 is used as a cross-linking curing agent in powder coating applications and will be present at a level of 2.8%. It is estimated the substance will be used in 80% of the 5000 tonnes of powder coatings used throughout Australia annually.

Spray powder coatings containing the substance will be applied to almost every type of metal panel or section including domestic appliances, pipes, window frames, filing cabinets, shelving and machine covers.

Release

PRIMID XL-552 will only be supplied to major paint manufacturing companies. The notifier did not have direct information on the paint manufacturers' customers but there may be expected to be a large number of these located in the major urban centres of Australia.

The notifier states that PRIMID XL-552 is encapsulated in the insoluble polymer leading to extremely low leaching potential. After the spray powder is applied to a metal surface by powder coating applicators, it is oven baked causing the formation of crosslinkages (covalent bonds) with the encapsulating polymer.

According to the notifier, powder coating manufacturing plants would dispose of 190 tonnes of powder coating waste per annum containing 4.8-5.7 tonnes of PRIMID XL-552. This is expected to be disposed of to a secure landfill.

It is estimated that the powder coating application plants utilise 98% of the powder coating with the remainder collected in recovery units. The notifer estimates that 80 tonnes (2-2.4 tonnes of PRIMID XL-552) of powder coating waste will be disposed of by application plants. There is no indication of the 1ocation and security status of the landfill sites, and these are expected to vary across Australia.

Fate

While a total of 8.0 tonnes of PRIMID XL-552 will be disposed of to landfill annually, it should be noted the substance is encapsulated (and possibly further crosslinked) in the insoluble polymer, and leaching potential is low..

. Biodegradation

The notifier has provided information on biodegradation studies for the notified substance by microorganisms. The Modified MITI test (OECD Guideline for testing chemicals No 301C, 1981) shows that PRIMID XL-552 is not readily biodegradable. The degree of biodegradation in activated sludge over the 28 day period, measured by biochemical oxygen demand, total organic carbon and analysis of the test substance by HPLC, was less than 5%. However, it should be stressed that this is a very stringent base level screening test in which negative results do not preclude biodegradability in the field (5).

Bioaccumulation

The notified substance's high water solubility, very low partition coefficient and low fat solubility indicate that it is unlikely to bioaccumulate. The company states that, although the PRIMID XL-552 is not readily biodegradable, bioaccumulation studies were not conducted because the substance has a low partition coefficient. This is acceptable.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1 Summary of Acute Toxicity studies with PRIMID XL-552

Test	Species	Outcome	Ref
Oral	Rat	LD_{50}>5000 mg/kg (M&F)	(6)
Dermal	Rabbit	LD_{50}> 5000 mg/kg (M&F)	(7)
Skin irritation	Rabbit	non irritant	(8)
Eye irritation	Rabbit	non irritant	(9)
Skin sensitisation	Guinea Pig	non-sensitising	(10)

9.1.1 Oral Toxicity (6)

A limit test was carried out in Crl:CD BR rats. Six males and six females were gavaged with an aqueous dispersion of PRIMID XL-552 at 5000 mg/kg. A control group received distilled water. Animals were observed for a period of 14 days. No deaths occurred during the period of the study. The only clinical signs observed were diarrhoea in the treated group four hours after administration. Necropsy revealed no gross changes. The oral LD_{50} for PRIMID XL-552 was > 5000mg/kg.

9.1.2 Dermal Toxicity (7)

Toxicity after dermal application was assessed in a group of six male and six female KFM-New Zealand White rabbits. A dose of 5000 mg/kg PRIMID XL-552, moistened with saline, was applied to the back of each animal 24 hours after shaving and covered with an occlusive dressing for 24 hours. The treated area was wiped then dried and the skin examined for any adverse reactions. Animals continued to be observed for a 14 day period after the application of the test article.

One male rabbit appeared emaciated and did not eat over a three day period. No deaths occurred during the study. No gross changes were noted at autopsy. The authors of the study observed erythema in some animals on day 1 following treatment. However,

the number of animals in which this occured was not stated. The dermal LD_{50} of PRIMID XL-552 was found in this test to be >5000 mg/kg in rabbits.

9.1.3 Skin Irritation (8)

Six New Zealand White rabbits were used to determine the skin irritant potential of PRIMID XL-552. Five hundred mg of PRIMID XL-552, moistened with 0.85% saline, was applied to the intact skin of the dorsal area of each of the six rabbits which had been shaved 24 hours previously. After application the skin was covered with an occlusive dressing for a 4 hour period. At the end of this time, the dressing was removed and the area washed with lukewarm tap water. The skin reaction was assessed at 1, 24, 48 and 72 hour and 7 day intervals after the removal of the dressing. Two animals showed very slight erythema at one hour but not at any subsequent intervals. There were no signs of oedema or corrosion. The chemical was considered to be non-irritant to the skin in this test.

9.1.4 Eye Irritation (9)

Eye irritation was measured by instillation of 0.1g PRIMID XL -552 into the left eye of 9 New Zealand White rabbits. The right eye was untreated and acted as a control. The treated and untreated eyes of three rabbits were rinsed for a 60 seconds period, 30 seconds after instillation. Eyes were examined 1, 24, 48 and 72 hours and 7 days after administration and irritation assessed. No signs of eye irritation were observed in any animals. Under the conditions of this test the chemical was considered to be non-irritant to the rabbit eye.

9.1.5 Skin sensitisation (10)

A maximisation test was carried out using female albino guinea pigs of the Dunkin/Hartley strain.

Dose finding tests determined that a concentration of 70% w/w was the maximum concentration that could be used topically. Accordingly, a 20% solution in water for irrigation was used for intradermal induction and a 70% solution in distilled water was used for topical induction and challenge.

A test group of twenty animals received intradermal injections, to a clipped dorsal site, of complete Freunds adjuvant of 20% PRIMID XL-552 in water for irrigation, and of 20% PRIMID XL-552 in a mixture of water for irrigation and Freunds adjuvant in equal parts. A control group of ten animals received identical treatment except that the second and third injections did not contain the test compound. No positive control group was included.

One week later the site was once more clipped and shaved and a patch saturated in PRIMID XL-552 in distilled water was placed on the treatment sites and held in place for 48 hours with an occlusive dressing. Plasters soaked only in distilled water were applied to the control group under identical circumstances.

Challenge took place three weeks after intradermal induction (two weeks after topical induction). Plasters soaked in 70% PRIMID XL-552 were applied to anterior sites on the flank. Plasters containing 35% PRIMID XL-552 were applied to posterior sites and held in place for 24 hours.

Challenge sites were evaluated 24, 48 and 72 hours after removal of patches. Two animals in the test group exhibited slight local erythema but of only a small area of the challenge site to which 70% PRIMID XL-552 had been applied. This was not considered sufficient evidence of sensitisation and PRIMID XL-552 was considered not to be a skin sensitiser in guinea pigs.

9.2 28 Day repeated dose study (11)

Groups of 5 male and 5 female Charles River (Crl CD R SD BR BAF Plus) rats received doses of 0, 10, 100 and 1,000mg/kg/day of PRIMID XL-552 in a dosage volume of 10 ml/kg/day for 28 days by intragastric intubation. Control animals received distilled water.

Animals were observed daily. At the end of the 4 week period the following examinations were carried out

. haematology;
. biochemistry;
. macroscopic examination following sacrifice;
. histopathologic examination of the adrenal glands, heart, kidneys, liver, spleen and any macroscopically abnormal tissue for the control group and the high dose group.

At the end of the study, male rats in the high dose group showed decreases in platelet and neutrophil counts which were statistically significant but still within normal range. Rats in the high dose group, both male and female, and males in the 100 mg/kg/day dose group showed decreased cholesterol values. Minor variations of serum phosphorous, and sodium and potassium ion concentration were also reported.

At autopsy, the liver and kidney weights were found to be increased in high dose males and females. Males receiving 1000 mg/kg/day showed a slightly decreased weight gain over the period of the study.

9.3 Mutagenicity

9.3.1 Salmonella typhimurium reverse mutation assay (12) OECD Guideline 471

PRIMID XL-552 was tested for mutagenicity in 5 strains of *Salmonella typhimurium*, TA1535, TA1537, TA1538, TA98 and TA100. Two independent experiments were performed. In both, concentrations of PRIMID XL-552 ranging between 50 and 5000 ug/plate were used with and without metabolic activation. Distilled water was used as a negative control. Positive controls were used as follows:

Without metabolic activation

9-aminoacridine, 80 ug/plate (TA 1537);
N-ethyl-N'-nitrosoguanidine, 3 ug/plate (TA 100);
N-ethyl-N'-nitrosoguanidine, 5 ug/plate (TA 1535);
2-nitrofluorene, 1 ug/plate (TA 98)
2-nitrofluorene, 2 ug/plate (TA 1538)

With metabolic activation

2-amimoanthracene, 0.5 ug/plate (TA 1538 and TA 98)
2-amimoanthracene, 1 ug/plate (TA 100 and TA 1535)
2-amimoanthracene, 2 ug/plate (TA 1537)

No increase in the number of revertant colonies per plate was observed with any concentration of the test compound up to 5000 ug/plate, with any of the strains used, with or without metabolic activation. Positive controls increased revertant colony numbers. The results indicate that PRIMID XL-552 is not genotoxic in *Salmonella typhimurium*.

9.3.2 Analysis of Metaphase Chromosomes (13)

Mammalian cells derived from Chinese hamster ovarian (CHO) tissue were incubated with PRIMID XL-552 for a four 4 period, with metabolic activation, or a twenty one hour period, without metabolic activation, Mitotic activity was stopped by the addition of colchicine to the culture 2 hours before the end of the incubation. Mitomycin C, 0.2 ug/ml, and cyclophosphamide, 20 ug/ml, served as positive controls and distilled water as the negative control. Concentrations of PRIMID XL-552, determined by an initial ranging study not to depress mitotic index, were from 6.25 to 3200 ug/ml. Subsequently a dose of 5000 ug/ml was tested. Cells were fixed, stained and assessed to determine clastogenicity.

Both the positive controls produced large increases in chromosomal abnormalities. The negative control and the test compound, in concentrations up to 5000 ug/ml, caused no increase in abnormalities. PRIMID XL-552 was found not to be clastogenic using CHO cells.

9.4 OVERALL ASSESSMENT OF TOXICOLOGICAL DATA

PRIMID XL-552 showed low acute oral and dermal toxicity in test animals. In rats, the oral LD_{50} was found to be >5,000mg/kg. Dermal LD_{50} in rabbits was >5000 mg/kg. PRIMID XL-552 was non-irritating in a skin irritation study, although some skin redness was reported in the dermal toxicity study. It is possible that this was a reflection of the greatly increased amount (circa x 20) of moistened chemical applied to the site, the pH (solutions

have a pH 9-10) and the greatly increased occlusion time. PRIMID XL-552 was not an eye irritant, can be classified as nonirritant to the skin and is not expected to be a respiratory irritant. It was non-sensitising in the guinea pig. PRIMID XL-552 was not mutagenic towards *Salmonella typhimurium* and did not cause chromosome aberrations *in vitro* in cells derived from the Chinese hamster ovary.

In the 28 day repeated oral dose study in rats, PRIMID XL-552 exhibited low systemic toxicity. Effects noted were a slightly decreased weight gain over the period of the study in males in the high dose group, minor changes in liver and kidney weights and some statistically, but not toxicologically significant, changes in biochemical parameters.

Diethanolamine, an impurity present at 1.8-2.8%, is a mild skin irritant and severe eye irritant in rabbits. It is a possible sensitising agent in humans. Neurotoxicity, liver and kidney damage have been demonstrated in animal studies.

10. Environmental Effects

Test	Species	Result
Acute toxicity	Rainbow trout 96h	LC_{50} = >1000 $mg.L^{-1}$
toxicity	*Daphnia magna* 48h	EC_{50} > 1000 $mg.L^{-1}$

Reports were provided and these indicate the above tests were satisfactorily conducted according to OECD Guidelines.

The aquatic toxicity test for *Daphnia magna* is part of the OECD Guidelines for Testing of Chemicals, Guideline no. 202: Daphnia spp., 24 h EC50. Acute Immobilisation Test. The notifier states that the Daphnia reproduction test was not attempted and claim that in view of the extremely low acute toxicity of PRIMID XL-552 this test would not reveal any effect. This is acceptable given a NOEL of 560 $mg.L^{-1}$.

The notifier states that no data were available for algae growth inhibition but they considered that the test would not show a significant effect given the no effect levels for rainbow trout (>1000 $mg.L^{-1}$) and *Daphnia magna*. This is acceptable given the very low toxicities to fish and daphnia, and the likely very low level of exposure to the aquatic compartment.

11. Environmental Hazard

Release from landfill

The main route of environmental exposure for the notified substance will occur when powder coating wastes are disposed of to landfill. Given its poor result in biodegradability screening tests and its hydrolytic stability, the substance appears likely to persist in the environment, although its hydroxyalkylamide structure would not be expected to resist degradation indefinitely. However, it is unlikely to leach from landfill as it is encapsulated in the polyester powder coating and further crosslinked (covalent bonds) after oven baking to metal substrates.

Ecotoxicity hazard

Ecotoxicity results indicate PRIMID XL-552 is practically non-toxic to fish and daphnia and unlikely to present either an acute or chronic hazard to aquatic invertebrates, freshwater fish and terrestrial mammals at likely environmental levels. Although no algal toxicity results were provided, the notified substance, in its proposed use, is also unlikely to present a hazard to algae. If PRIMID XL-552 reaches the aquatic compartment it is extremely unlikely to bioaccumulate to toxic levels given its very high water solubility and low octanol water partition coefficient.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The main occupational exposure to PRIMID XL-552 is expected to be by via inhalation or by skin contact . The chemical is not a skin or eye irritant or a skin sensitiser and would not be expected to be a respiratory irritant. Particles of PRIMID XL-552 are larger than respirable size. However, exposure, as to all dusts, should be minimised by engineering measures such as ventilation and if necessary by protective clothing. Precautions for use of PRIMID XL-552 should also take the presence of the impurity, diethanolamine, into account.

PRIMID XL-552 is non flammable. However, it may react with strong oxidising agents.

The potential for public exposure to PRIMID XL-552 is negligible. Use of the product as a crosslinking curing agent in powder coating applications is restricted to confined industrial settings, where it is incorporated within a solid, water insoluble, high molecular weight polymer matrix.

The use pattern outlined by the notifier and the toxicological profile provided suggests that PRIMID XL-552 presents a low public health hazard.

13 RECOMMENDATIONS FOR THE CONTROL OF PUBLIC AND WORKER EXPOSURE

To minimise public and worker exposure to PRIMID XL-552 the following guidelines and precautions should be observed:

- Precautions should be taken to minimise generation of dust. Good exhaust ventilation should be supplied, sufficient to maintain the level of dust at or below that recommended for nuisance dusts 10 mg/m^3 (4).

- Workers weighing or mixing PRIMID XL-552 with other raw materials should wear impervious rubber gloves conforming to Australian Standard no 2161-1978 (14), dust masks or face shields conforming to Australian Standards (15,16 and 17).

- workers micronising extruded product or handling the micronised material should wear dust masks.

- Material safety data sheets should be available to all workers using PRIMID XL-552 and products containing PRIMID XL-552.

- contact with strong oxidising agents should be avoided.

- safety measures taken in the use of PRIMID XL-552 should recognise the presence of the contaminant, diethanolamine. Airborne concentrations should be monitored and levels maintained below the Exposure Standard of 13 mg/m^3 (3ppm) or appropriate protective clothing which conforms to Australian Standards (14,15,16 and 17) should be worn.

15. material safety data sheet

The material safety data sheet for PRIMID XL-552 is in accordance with the Worksafe Australia format (18).

16. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals Notification and Assessment Act 1989* (the Act) secondary notification of PRIMID XL-552 shall be required if any of the circumstances stipulated under section 64 (2) of the Act arise. If there is an increase in public exposure secondary notification and further information may be required to assess public health hazard.

REFERENCES

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(4) National Occupational Health and Safety Commission, *Exposure standards for Atmospheric contaminants in the Occupational Environment* 2nd Edition, AGPS, Canberra, 1991

(5) Nyholm N (1991), "The European System of Standardised Legal Tests for Assessing the Biodegradability of Chemicals", Environmental Toxicology and Chemistry, **10**, p1237-1246.

(6) Monomer QM-552 PMN. Acute Oral Toxicity study in Male and Female Rats. Data on File Rohm and Haas Company, 727 Norristown Road, Spring House, Pennsylvania, 19477 USA

(7) Monomer QM-552 PMN. Acute Dermal Toxicity study in Male and Female Rabbits. Data on File Rohm and Haas Company, 727 Norristown Road, Spring House, Pennsylvania, 19477 USA

(8) Monomer QM-552 PMN. Skin Irritation Study in Rabbits. Data on File Rohm and Haas Company, 727 Norristown Road, Spring House, Pennsylvania, 19477 USA

(9) Monomer QM-552 PMN. Eye Irritation Study in Rabbits. Data on File Rohm and Haas Company, 727 Norristown Road, Spring House, Pennsylvania, 19477 USA

(10) Delayed contact hypersensitivity in the guinea-pig with QM-552. Data on File Rohm and Haas Company, European Operations, Chesterfield House, Bloomsbury Way, LONDON WC1A 2TP, ENGLAND.

(11) Twenty-eight day Oral Toxicity in the Rat with QM 552. Data on File Rohm and Haas Company, European Operations, Chesterfield House, Bloomsbury Way, LONDON WC1A 2TP, ENGLAND.

(12) QM 552: Bacterial Mutation Assay. Data on File Rohm and Haas Company, European Operations, Chesterfield House, Bloomsbury Way, LONDON WC1A 2TP, ENGLAND.

(13) Analysis of metaphase chromosomes obtained from CHO cells cultured in vitro and treated with QM-552. Rohm and Haas Company, European Operations, Chesterfield House, Bloomsbury Way, LONDON WC1A 2TP, ENGLAND

(14) Australian Standard 2161-1978 *Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)*, Standards Association of Australia Publ, Sydney 1978.

(15) Australian Standard 1337-1984 *Eye Protectors for Industrial Applications*, Standards Association of Australia Publ, Sydney 1984.

(16) Australian Standard 1336-1982 *Eye Protection in the Industrial Environment*. Standards Association of Australia Publ, Sydney 1982.

(17) Australian Standard 1716-1984 *Respiratory Protective Devices*, Standards Association of Australia Publ, Sydney 1978.

(18) National Occupational Health and Safety Commission, *Guidance Note for Completion of a Material Safety Data Sheet* 2nd Edition, AGPS, Canberra, 1990