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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

PV FAST YELLOW HGR

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

PV FAST YELLOW HGR

1. IMPORTER

Hoechst Australia Ltd., 606 St. Kilda Road, Melbourne. Victoria 3004

2. IDENTITY OF THE CHEMICAL

Trade name PV Fast Yellow HGR

Molecular weight: 525.0

Spectral data: UV/VIS spectrum (major absorption bands at 250-470 nm);

IR spectrum (strongest bands at 1543 cm^{-1};1487 cm^{-1}; 1267 cm^{-1}; 1252 cm^{-1}; 1242 cm^{-1}; 1223 cm^{-1}; 1198 cm^{-1}; 1171 cm^{-1}; 1128 cm^{-1}; 1061 cm^{-1});

NMR spectral data were also provided.

PV Fast Yellow HGR is classified as a non-hazardous chemical to humans because the toxicological data submitted suggest that it is unlikely to produce any toxic effects. For this reason, its chemical name, Chemical Abstract Service Registry Number, molecular formula and structural formula have been exempted from publication.

3. PHYSICAL AND CHEMICAL PROPERTIES

PV Fast Yellow HGR is a yellow powder at 20°C and 101.3 kPa.

Melting Point/Boiling Point:	melting Point: >320°C
Density:	1.64 (D^{23}_4)
Water Solubility:	53 mg/L at 20°C
Hydrolysis as a function of pH:	stable to hydrolysis at pH 4, 7 and 9
Fat Solubility:	insoluble in fat at 37°C
Flammability Limits:	not flammable.
Autoignition Temperature:	360°C
Explosive Properties:	not explosive due to flame, shock or friction.
Reactivity:	not an oxidizing agent. Incompatibility, instability and decomposition products, not known.

Comments on physico-chemical properties

The **Vapour Pressure** was not measured because the chemical is a salt.

The **Partition Coefficient** was not measurable because the pigment is virtually insoluble in water.

No data were provided for **Dissociation Constant** and **Adsorption/Desorption** on the grounds that:

. information on these characteristics was not available from the manufacturer and was not required for registration of the pigment in the European Community (EC);

. existing data confirm that the pigment has low water and fat solubility; and

. there is a low potential for quantities of the pigment to be released to the environment.

The literature suggests that highly sulphonated dyes adsorb to sediment (1) and ready dissociation in aqueous solution is indicated by the presence of the two sulphonate groups.

The reasons for the omission are acceptable.

4. METHOD OF DETECTION AND DETERMINATION

Argentometric Titration; High Pressure Liquid Chromatography; Titanometry.

5. PURITY OF THE CHEMICAL

Degree of purity: 90% w/w (range 85% - 98%)

Toxic or hazardous impurities: None

Non-hazardous impurities: Water: approx 6% w/w
Inorganic impurities: < 6.5% w/w
(NaCl < 0.5%, Na_2SO_4 < 0.5%)

Additives/Adjuvants: None

6. INDUSTRIAL USES

PV Fast Yellow HGR is to be imported by Hoechst Australia Ltd. from Hoechst A.G., Frankfurt am Main, Germany. All quantities of the pigment are to be supplied to reformulators for the production of pigmented polyolefin masterbatches for ultimate use in the production of coloured plastic products for domestic or industrial use. PV Fast Yellow HGR will be present in the reformulated products at concentrations of <60% w/w.

7. OCCUPATIONAL EXPOSURE

7.1 Process Description

The new pigment will be reformulated into masterbatch formulations at six to ten sites in Australia.

At the reformulators' premises, the pigment will be removed from the original packaging, weighed under dust extraction hoods and then mixed in an enclosed mechanical mixer with other raw materials determined by the formulation. The raw materials mixture will then be conveyed in a closed container (bin) to a feed chute for delivery into an extruder which will incorporate the pigment into the plastic substrate. Delivery into the extruder will take place under dust and fume extraction. After reformulation, the reformulated product in the form of plastic granules will be mechanically packaged into plastic bags each containing 25 kg of granules.

7.2 Occupational Exposure

As the new pigment will be imported and transported in sealed containers, significant risk is not anticipated from accidental spillage during transport, or storage at Hoechst Australia Ltd.. Potential exposure may take place at the reformulators' premises and it is anticipated that this will occur on an irregular basis throughout the year, dependent on production requirements.

Potential exposure to the new pigment at the reformulators' premises may take place during its handling and usage. The major route of direct contact with the new pigment would be through the skin. Production operators responsible for removing the pigment from the original packaging, the weighing and mixing of the pigment and the cleaning of the equipment, may come into direct contact with the pigment if personal protection and engineering controls are not implemented. After mixing, the mixture of raw materials will be conveyed in a closed container (bin) to a feed chute for delivery into an extruder, which will incorporate the pigment into the plastic substrate. The notifier states that all of the new pigment will be incorporated into the masterbatch formulations and that after extrusion, the pigment will be bound within the matrix of the plastic rendering it not readily extractable thus presenting a very low risk of exposure to workers and end-users who handle the granular masterbatches or the moulded finished products.

8. PUBLIC EXPOSURE

Under normal conditions, the potential for public exposure to PV Fast Yellow HGR is low as the pigment will be imported in sealed cartons and after reformulation, all of the pigment will be bound within a plastic matrix and is not readily extractable from granular masterbatches or moulded finished products. In addition, used plastic bags and waste pigment reformulations that will not be reused will be disposed of in a regulated land fill.

9. ENVIRONMENTAL EXPOSURE

. Release

The notifier states that all of the pigment will be incorporated into the polyolefin masterbatches. Disposal of the reformulated product to landfill may occur in the event of accidental spillage and if residual reformulated product in the extruding equipment is not reused by plastic recyclers. After reformulation, all subsequent manufacturing processes will take place with the pigment bound within the plastic matrix.

. Fate

The notifier states that after incorporation of the pigment into the polyolefin substrate, the pigment is encapsulated within the plastic matrix and it is virtually impossible for the pigment to be released to the environment during normal use. The pigment will therefore not be readily extractable if the granular masterbatches or moulded finished products are exposed to the environment as could happen in landfill waste sites.

The pigment is likely to form oxides of nitrogen and carbon on combustion.

Results from a biodegradability screening test (2) indicate that PV Fast Yellow HGR is not readily biodegradable as degradation of 35% was calculated after 35 days. This is only a screening test and does not necessarily imply poor degradation in the environment (3).

A bioaccumulation study was not provided by the notifier on the grounds that the pigment was virtually insoluble in water and insoluble in fat. This is acceptable as the negligible fat solubility indicates that it is unlikely to bioaccumulate. In addition, the proposed usage of the pigment will also ensure that minimal quantities are released to the environment and be available for bioaccumulation.

10. EVALUATION OF TOXICOLOGICAL DATA

10.1 Acute Toxicity

Table 1. Summary of acute toxicity of PV Fast Yellow HGR

Test	Species	Outcome	Ref.
Oral	Rat	LD_{50}: >2000mg/kg	4
Dermal	Rat	LD_{50}: >2000mg/kg	7
Skin irritation	Rabbit	Slight irritation, reversible within 24 hr	10
Eye irritation	Rabbit	Slight irritation, reversible within 48 hr	13
Skin sensitisation	Guinea Pig	Non sensitising	16

10.1.1 Oral Toxicity (4)

PV Fast Yellow HGR in sesame oil was tested at a single dose level of 2000 mg/kg bodyweight in five male and five female *Wistar* rats by oral gavage according to the *OECD Guidelines for Testing of Chemicals No: 401* (5) and the *EEC Guideline B.1* (6). The animals were observed for 14 days. The faeces of both sexes were discoloured yellow from Day 1 to Day 3 post-treatment. Gain in body weight was not impaired. No deaths were observed following treatment and no toxic signs were noted. The animals

killed at the end of the observation period showed no macroscopically visible changes.

The results of this study indicate a median lethal dose (LD_{50}) of >2000 mg/kg bodyweight for PV Fast Yellow HGR in both male and female rats.

10.1.2 Dermal Toxicity (7)

PV Fast Yellow HGR moistened with polyethylene glycol 400 was applied by occlusive epidermal application at a dose level of 2000 mg/kg to the shaved intact dorsal skin of five male and five female *Wistar* rats for 24 hours. This study was performed according to the *OECD Guidelines for Testing of Chemicals No: 402* (8) and the *EEC Guideline B.3* (9). The animals were observed for 14 days. One day post-exposure, the application sites were discoloured yellow. The gain in body weight of one male animal was slightly decreased during the whole study period. Gain in body weight of the other animals was not impaired. No deaths were observed following treatment and no toxic signs were noted. The animals killed at the end of the observation period showed no macroscopically visible changes.

The results of this study indicate a median lethal dose (LD_{50}) of >2000 mg/kg bodyweight for PV Fast Yellow HGR in both male and female rats.

10.1.3 Skin Irritation (10)

A single dose of 0.5 g of PV Fast Yellow HGR, moistened with polyethylene glycol 400, was applied to the intact skin of the shaved area of three (*New Zealand albino*) rabbits for four hours. Skin reaction was assessed 30-60 minutes, and 24, 48, and 72 hours after removal of the patches. The reaction was assessed according to the numerical scoring system described in the *OECD Guidelines for Testing of Chemicals No: 404* (11) and *EEC Directive B.4* (12). The application sites were discoloured yellow and slight erythema which was reversible within 24 hours was the only effect noted.

The results of this study, indicate that PV Fast Yellow HGR is a slight skin irritant in rabbits at the concentration tested.

10.1.4 Eye Irritation (13)

A single dose of 0.1 g of PV Fast Yellow HGR was instilled into the conjunctival sac of the left eye of each of three (*New Zealand albino*) rabbits, with the untreated right eye acting as control. The eyes were examined 1, 24, 48 and 72 hours post-treatment. Eye irritation was scored according to the numerical scoring system described in the *EEC Directive B.5* (14) and the *OECD Guidelines for Testing of Chemicals No: 405* (15). One hour post-exposure, slight redness and chemosis of the conjunctivae were observed in all three treated eyes. Red iris and yellow discharge were observed in all three animals. Twenty-four hours after treatment, conjunctival redness in two animals was still observed. All signs of irritation subsided 48 hours post-exposure. No corneal lesions were observed in any of the animals.

The results from this study indicate that PV Fast Yellow HGR is a slight eye irritant in rabbits at the concentration tested, but the effect was reversible within 48 hours.

10.1.5 Skin Sensitisation (16)

The Magnusson & Kligman Maximisation Test was used. Skin reaction was scored according to the *OECD Guidelines for Testing of Chemicals No: 406* (17) and the *EG-Guideline B.6* (18).

In the preliminary study, the test substance, PV Fast Yellow HGR in petrolatum oil, was administered by intradermal injection and epidermal application to the clipped flanks of *Pirbright-White* [*DHPK (SPFLac)*] guinea pigs . A 1% concentration of PV Fast Yellow HGR in Petrolatum was chosen for intradermal injection in the main test. The concentration selected for the challenge was 25%.

In the main test, 10 animals (female) in the treatment group and five animals (female) in the control group were used. At the beginning of the induction period, each animal in the treatment group was first induced by intradermal injection at three sites (Site 1: injection 50% Freund's Adjuvant only; Sites 2 & 3: 1% PV Fast Yellow HGR in semi-liquid paraffin and in 50% Freund's Adjuvant respectively). Nine days later, the same animals were again induced with 25% PV Fast Yellow HGR in petrolatum at the same sites. Freund's Adjuvant (with and without test substance) caused moderate erythema, oedema, indurations and necrosis. The application sites treated with the test substance showed no sign of irritation. On Day 11, eschar formation, encrusted skin and

necrosis were observed at the sites previously treated with Freund's Adjuvant. Twenty-two days after intradermal injection, each animal (including controls) was challenged with 25% PV Fast Yellow HGR in petrolatum for 24 hours. No signs of sensitisation were observed in either the control or treated groups 24 and 48 hours after removal of the dressing.

The results of this study indicate that PV Fast Yellow HGR is non sensitising in guinea pigs.

10.2 Repeated Dose Toxicity (20)

PV Fast Yellow HGR was administered by oral gavage to groups of five male and five female *Wistar* rats at dose levels of 0, 62.5, 250, 1000 mg/kg b.w. per day for 28 days. The observations and examinations were carried out in accordance with the *OECD Guidelines for Testing of Chemicals No: 407* (21). Gain in bodyweight, behaviour, general health condition and food and water consumption were unaffected by treatment. No deaths were noted. Haematological examinations revealed no abnormalities. Clinical chemistry showed decreased serum inorganic phosphorous, increased alpha-1-globulin, as well as decreases in alpha-3-globulin and beta-1-globulin fractions in females at the highest dose level. Decreased urinary specific gravity was observed at the highest dose level in both sexes. Organ weights were not affected. No treatment-related macroscopically visible changes were found at necropsy. Histopathological examinations revealed no treatment-related changes.

10.3 Genotoxicity

Table 2. Summary of Genotoxicity studies with PV Fast Yellow HGR

Test	Dose range	Outcome	Ref.
Salmonella typhimurium Reverse Mutation Assay	4 - 5000 µg/plate	negative	22
In vivo mouse micronucleus assay	2000 mg/kg	negative	24

10.3.1 *Salmonella typhimurium* Reverse Mutation Assay (22)

PV Fast Yellow HGR at dose levels of 4 ug/plate to 5000 µg/plate was tested for mutagenicity with strains TA 100, TA 1535, TA 1537, TA 1538 and TA 98 of *Salmonella typhimurium*, both in the absence and presence of an exogenous metabolising system. The test was carried out in accordance with the *OECD Guideline for Testing of Chemicals No: 471* (23). In the absence or presence of metabolic activation, PV Fast Yellow HGR did not produce significant increases in the number of revertant colonies. In contrast, the positive controls - sodium azide, 9-aminoacridine, 2-nitrofluorene, benzo[a]pyrene and 2-aminoanthracene, showed the expected increase in the number of revertant colonies.

The results of this study suggest that PV Fast Yellow HGR is not genotoxic under the experimental conditions reported.

10.3.2 Micronucleus test (24)

PV Fast Yellow HGR at dose levels of 0 and 2000 mg/kg bodyweight was administered orally by gavage to male and female *NMRI* mice according to the *OECD Guideline for Testing of Chemicals No: 474* (25). Cyclophosphamide at dose level of 50 mg/kg bodyweight was used as positive control. The incidence of micronucleated polychromatic erythrocytes with PV Fast Yellow HGR was within the range of the negative control. In contrast, the positive control showed statistically significant increase in the number of polychromatic cells with micronuclei.

The results of this study suggest that PV Fast Yellow HGR is not genotoxic under the experimental conditions reported.

10.4 Overall Assessment of Toxicological Data

PV Fast Yellow HGR has low acute oral and dermal toxicity (oral LD_{50} in rats: >2000 mg/kg; dermal LD_{50}: >2000 mg/kg). Tests in rabbits show slight, reversible irritation to the skin and eyes. No evidence of skin sensitisation was found. A short-term repeated dose toxicity study in rats by oral gavage shows that at 1000 mg/kg bodyweight, decreased serum inorganic phosphorous, increased alpha-1-globulin, as well as decreases in alpha-3-globulin and beta-1-globulin fractions were observed in females, and decreased urinary specific gravity was observed in both sexes.

PV Fast Yellow HGR was found to be non-genotoxic in both the *Salmonella typhimurium* reverse mutation test and *the in vivo* mouse micronucleus assay.

11. Assessment of public and Occupational Health and Safety Effects

Animal tests indicate that PV Fast Yellow HGR can cause slight, reversible irritation to the skin and eyes, but it is not a skin sensitiser. Such reactions can be avoided in the workplace by the use of personal protection equipment to prevent direct contact with the pigment. Personal protection is recommended. The notifier states that the pigment is not known to have caused any health conditions or to affect any existing health conditions, and no work related effects on health have been reported. However, it should be noted that the pigment has not been produced over a long period of time nor widely used thus current experience with the pigment is limited.

The physico-chemical data indicate that the pigment is a solid with low water solubility, has a high melting point and autoignition temperature,and is not flammable nor explosive. Therefore, it is anticipated that the pigment will not present any safety hazard to workers.

Due to low public and occupational exposure under correct handling and use procedures, the pigment is unlikely to present any significant health or safety hazard to the public and workers.

12. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Table 3. Summary of ecotoxicity of PV Fast Yellow HGR

Test	Species	Outcome	Reference
Acute toxicity	*Zebrafish*	96h LC_{50}: >500 mg/L	26
Acute immobilisation	*Daphnia magna*	24h EC_{50}: 1000 mg/L	27

The above studies were carried out in accordance with the *OECD Guidelines for Testing of Chemicals* (28, 29). As the pigment has low water solubility, solubilising agents were used to perform the tests. The results of these tests demonstrate that the pigment is practically non-toxic to the species tested.

The acute immobilisation test is part of the *OECD Guidelines for Testing of Chemicals No: 202: Daphnia spp., 14-Day Reproduction Test* (29). The reproduction part of the test was not carried out by the notifier due to poor water solubility, with problems of sedimentation of the pigment particles which would affect the ability to obtain results from the study. Assuming a safety factor of 1000 for the acute immobilisation result, the predicted chronic toxicity for *daphnia magna* would be >1 ppm, which given the remote likelihood of exposure of the pigment to the aquatic compartment, would be several orders of magnitude higher than an estimated environmental concentration in water. Therefore a reproductive test will not be required.

No data were provided for algal growth inhibition on the grounds that the algal toxicity test was not required for registration in the European Community (EC), and the poor water solubility of the chemical will affect the ability to obtain results from these studies. While there are other methods of measuring changes in algal growth, the omission of such data is acceptable as a survey of fish toxicity data on over 3000 commercial products by the Ecological and Toxicological Association of the Dyestuffs

Manufacturing Industry (ETAD) indicates that the majority of dyes are not very toxic to fish (30), and algal growth inhibition tests of 56 dyestuffs showed close parallels with fish toxicity data (30). Based on the above information and the notified pigment fish toxicity result, it is unlikely that the notified pigment will be toxic to algae. Exposure to the aquatic compartment is also likely to be very limited.

13. ASSESSMENT OF ENVIRONMENTAL HAZARD

The ecotoxicity results indicate that PV Fast Yellow HGR is unlikely to present either an acute or chronic hazard to aquatic invertebrates, freshwater fish and terrestrial mammals as it has low acute toxicity, is not readily extractable from granular masterbatches or moulded finished products and limited quantities are likely to reach the aquatic compartments.

The notifier does not foresee the likelihood of landfill disposal, given the formulation processes and the insignificant likelihood of spillage.

14. ASSESSMENT OF MATERIAL SAFETY DATA SHEETS (MSDS)

The MSDS for PV Fast Yellow HGR (Attachment 1) has been compiled according to Worksafe Australia format (31).

15. RECOMMENDATIONS FOR THE CONTROL OF OCCUPATIONAL EXPOSURE

To minimise worker exposure to the PV Fast Yellow HGR, the following guidelines and precautions should be observed:

. the factory should be well ventilated and engineering controls such as local exhaust venlilation should be used in the weighing, mixing and extrusion areas;

. enclosed systems should be used for mixing, delivery and extrusion processes;

. personal protection equipment which comply with Australian standards should be worn such as safety goggles (32), impermeable gloves (33), protective clothing and when there

is insufficient ventilation, disposable particulate respirator (34);

. safe work practices should be implemented to avoid spillages or the generation of a dust cloud;

. spillages should be promptly picked up with a vacuum cleaner;

. storage and transportation of the pigment should be in closed containers; and

. a copy of the MSDS for the notified chemical and its reformulated products should be easily accessible to employees.

16. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of PV Fast Yellow HGR shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

17. REFERENCES

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4. AcuteOral Toxicity of PV Fast Yellow HGR. Data on file, Hoechst A.G., Germany. Report No. 90.0991, 1990.

5. OECD Guidelines for Testing of Chemicals No: 401, 1987; Acute Oral Toxicity.

6. EEC Guideline B.1, Acute oral Toxicity in Council Directive 84/449/EEC.

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8. OECD Guidelines for Testing of Chemicals No: 402, 1987; Acute Dermal Toxicity.

9. EEC Guideline B.3, Acute Dermal Toxicity in Council Directive 84/449/EEC.

10. Primary Dermal Irritation of PV Fast Yellow HGR. Data on file, Hoechst A.G., Germany. Report No. 90.1028, 1990.

11. OECD Guidelines for Testing of Chemicals No: 404, 1981; Acute Dermal Irritation/Corrosion.

12. EEC Directive B.4, *Acute Toxicity Skin Irritation*, Directive 84/449/EEC.

13. Primary Eye Irritation of PV Fast Yellow HGR. Data on file, Hoechst A.G., Germany. Report No. 90.1031, 1990.

14. EEC Directive B.5. *Acute Toxicity Eye Irritation*, Directive 84/449/EEC.

15. OECD Guidelines for Testing of Chemicals No: 405, 1987; Acute Eye Irritation/Corrosion.

16. Skin Sensitising Testing of PV Fast Yellow HGR. Data on file, Hoechst A.G., Germany. Report No. 90.0968, 1990.

17. OECD Guidelines for Testing of Chemicals No: 406, 1981; Skin Sensitization.

18. EG-Guideline B.6. Acute Toxicity Sensitization of the Skin, Directive 84/449/EWG.

19. Directive 83/467/EWG: Commission Directive of 29 July 1983.

20. Subacute Oral Toxicity of PV Fast Yellow HGR. Data on file, Hoechst A.G., Germany. Report No. 90.0943, 1990.

21. OECD Guidelines for Testing of Chemicals No: 407, 1981; Repeated Dose Oral Toxicity.

22. Study of the Mutagenic Potential in Strains of *Salmonella typhimurim* (Ames Test) With PV Fast Yellow HGR. Data on file, Hoechst A.G., Germany. Report No. 88.2131, 1989.

23. OECD Guidelines for Testing of Chemicals No: 471, 1983; Genetic Toxicity: *Salmonella typhimurim*, Reverse Mutation Assay.

24. Micronucleus Test in Male and Female *NMRI* mice after Oral Administration with PV Fast Yellow HGR. Data on file, Hoechst A.G., Germany. Report No. 89.0508, 1989.

25. OECD Guidelines for Testing of Chemicals No: 474, 1983; Genetic Toxicity, Micronucleus Test.

26. 96-hour Acute Toxicity Study in *Zebra* fish (*Brachydanio rerio)* of PV Fast Yellow HGR. Data on file, Hoechst A.G., Germany. Report No.90.1014, 1990.

27. Static Acute Toxicity Test for *Daphnia magna* with PV Fast Yellow HGR. Data on file, Hoechst A.G., Germany. Report No. 84/449/EEC

28. OECD Guidelines for Testing of Chemicals No: 203, 1981; Fish Acute toxicity Test.

29. OECD Guidelines for Testing of Chemicals No: 202, 1981; *Daphnia sp*., 14-day Reproduction Test (Including an Acute Immobilisation Test).

30. Anliker R., *Organic colourants- Interpretation of Mammalian-, Geno-, and Ecotoxicity Data in Terms of Potential Risks*. In: Toxic hazard assessment of chemicals 9Ed. Richardson M). Royal Society of Chemistry, 1986.

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