File No: NA/242

Date: April 4, 1995

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

C.I. ACID YELLOW 256

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989,* and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Human Services and Health.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

C.I. ACID YELLOW 256

1. APPLICANT

Sandoz Australia Pty. Ltd. have submitted a limited notification for assessment of an acid dye, C.I. Acid Yellow 256, which is a component of a formulation marketed as Nylosan Yellow E-2RL SGR.

2. IDENTITY OF THE CHEMICAL

- has been classified as hazardous by Worksafe Australia due to its skin sensitisation properties. However, for commercial reasons, the identity, impurities and methods of detection and determination have been granted exemption from the Full Public Report and Summary Report. The conditions of this being permitted are:

- The chemical name C.I. Acid Yellow 256 dye be used to identify the substance in the public reports and the MSDS,

- The relevant employee unions shall be informed of the conditions of use of C.I. Acid Yellow 256,

- The full chemical name shall be provided to any health professionals in the case of a legitimate need where exposure to the chemical may involve a health risk,

- The full chemical name shall be provided to those on site who are using the chemical and to those who are involved in planning for safe use, etc. in the case of a legitimate need,

- The Director of NICNAS will release the full chemical name etc in the case of a request from a medical practitioner,

- Confidentiality will expire after a 3 year period,

- That the chemical be identified as a sensitiser in the Health Effects Section of the MSDS, and that reference to its assessment by NICNAS be made on the MSDS,

- These conditions shall be published in the Chemical Gazette.

Trade name: Nylosan Yellow E-2RL SGR, which is a formulation containing the notified chemical, C.I. Acid Yellow 256

Molecular weight: 534

Method of detection and determination:

The active substance can be detected qualitatively with UV/Vis, IR and NMR spectroscopy, and quantitatively by titanometric titration. Inorganic impurities can be determined argentometrically, and by the Karl Fischer method. Organic impurities can be detected by HPLC.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Solid orange, fine granules
Odour:	None
Melting Point/Boiling Point:	> 250°C
Density:	1480 kg/m^3 at 20°C
Vapour Pressure:	Negligible based on the high MW and high melting point
Water Solubility:	14 g/L at 20°C/pH 6.7 - 7.8
Fat Solubility:	< 0.084 mg/100 g fat at 37°C
Partition Co-efficient (n-octanol/water) logP_{ow}:	-1.7 at 20°C
Hydrolysis as a function of pH:	Not performed. Hydrolysis has not been observed during the application process. The dye is recommended for application processes which have to be carried out at pH between 4.0 and 9.0, and at temperatures up to 100°C. The dye is stable within these limits.
Adsorption/Desorption:	Expected to have low affinity
Dissociation Constant pKa**:**	Not determined
Flash Point:	Solid, non-volatile substance
Flammability Limits:	Not flammable
Autoignition Temperature:	No self ignition up to 400°C
Explosive Properties:	No thermal, friction or mechanical sensitivity shown
Reactivity/Stability:	No known oxidizing properties
Particle size distribution:	range - 1.2 to 88 µm 15% are < 15 µm

Surface Tension: 60.6 mN/m at 20°C

Comments on physico-chemical properties:

It is expected that the chemical will have negligible vapour pressure due to high melting point and high molecular weight.

As noted above, hydrolysis has never been observed during the application process in which the dyestuff has been involved. The presence of an amide functionality is noted.

In view of the high water solubility and low partition coefficient of the chemical it is expected to have a low affinity to soil.

The dissociation test was not supplied. The dye is a sulphonic acid salt and is expected to have a dissociation constant typical for this functionality.

4. PURITY OF THE CHEMICAL

Degree of purity : typical concentration is 78%
lower limit is 68%
upper limit is 88%

The notified chemical comprises between 70 and 80% of the formulation Nylosan Yellow E-2RL SCR.

Toxic or hazardous impurity/impurities: None

Non-hazardous impurity/impurities (> 1% by weight):

Sodium Chloride	10-20%
Water	1-5%
4 Known Coloured By-products	0.68%
Unknown by-products	3.32%

Additives/Adjuvants: None

5. INDUSTRIAL USE

C.I. Acid Yellow 256 is to be used as a textile dye for polyamide and wool. The notified chemical will be imported at quantities of < 1000 kg/year over the next 5 years.

6. OCCUPATIONAL EXPOSURE

The chemical is to be used as a textile dye for polyamide fibre and wool. Customers will receive the dye in 25 kg steel drums or if they order a smaller quantity, in rigid plastic containers. Any re-packing will carried in the company's warehouse, exposing one storeman.

Eight dyehouses (estimate) will be using this product. One storeman and one operator will be exposed to the notified chemical at each dye house. After weighing out, the dye is dissolved in water in a pre-

mix tank and added to the dyebath by pump or gravity feed, a procedure taking about one hour per day. The number of days on which this will occur could not be reliably estimated.

The dye is imported in a non-dusting form, that is, fine granules. Weighing out will most likely not be conducted using local exhaust ventilation and the dyebaths are usually, but not always enclosed.

7. PUBLIC EXPOSURE

No public exposure is expected to occur during its industrial use if batching and dyeing procedures were to be conducted either under local exhaust ventilation or within a closed system.

Waste C. I. Acid Yellow 256 may be disposed of by landfill or incineration. Unfixed residues from dyeing operations will enter the aquatic environment from the textile mills, with subsequent treatment at sewage treatment plants. Any C. I. Acid Yellow 256 in the effluent is expected to be at a low concentration, since the dye is exhausted onto the fibre at a rate of 95% (wool) and 99% (polyamide). 5% of the dye used could be discharged into the effluent of the dye houses where it is used. The notifier has calculated, on a basis of a batch size of 100 kg of fabric, using 1 kg of Nylosan Yellow E-2RL SGR per batch, that the effluent concentration from the dye bath will be 4 ppm. The manufacturer further claims that there will be a further dilution, of the order of at least 1 in 10, in the waste treatment water of the dye house. Dye lost to the sewage system is thus estimated to be < 1 ppm. Disposal of the notified chemical is not expected to result in significant public exposure.

Potential public contact with the dye may be extensive, due to its proposed use in clothing fabrics. However, due to its expected low concentration in finished fabric, exposure levels would be low. Further, due to its fairly high molecular weight (533), its low fat solubility, and the fact that it is bound to textile fibres, if dermal absorption were to occur, it would not be expected to be significant.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier has indicated without supporting evidence that the dye will be exhausted onto wool or polyamide fibre at a rate of 95 and 99%; the remainder will be rinsed off into wastewater. Therefore, unfixed residues from dyeing operations will enter the aquatic environment from the textile mills and subsequent treatment at sewage treatment plants.

Any waste dye will be disposed of in landfill or by incineration.

The dye that is chemically bound to clothing fibres is not expected to adversely impact on the environment.

Fate

As a result of the dye's high water solubility, low K_{ow}, and hydrolytic stability, it is likely that quantities will remain in the aquatic phase.

The chemical was tested for its biodegradability using two standard test methods. The ready biodegradability study (EEC test method C.6) of YELLOW E-JD 3442 in a 28-day closed bottle test gave negative results: -35% and -14% at nominal concentrations of 1 and 3 mg/L, respectively. The result indicates that YELLOW E-JD 3442 is not readily biodegradable in the closed bottle test and is unlikely to undergo rapid biodegradation in the environment (1).

A second biodegradation study of YELLOW E-JD 3442 was provided using the Inherent Biodegradability Modified Zahn-Wellens Test (OECD TG 302B). The test article was dissolved in the test medium (micro-organisms from secondary effluent) at concentrations of 223.5 and 230 mg/L. YELLOW E-JD 3442 was degraded under the test conditions by 34% within 28 days. The positive result indicates that the chemical has the potential for biodegradation and will not persist indefinitely in the environment (1).

The above biodegradation studies indicate that the notified chemical is unlikely to significantly biodegrade in sewage treatment plants due to the relatively short retention time.

After treatment in the sewage plant, the dye will enter either freshwater or marine environments in solution. Biodegradation under aerobic conditions is likely to be slow. Azo dyes are susceptible to reductive degradation under anaerobic conditions that are characteristic of sediments (2). The half-life of this form of degradation was found to be between 2 and 16 days for several sulphonic dyes (3). Thus no significant increase in concentration over time is expected. One possible route for the dye to enter the sediments is by precipitation of its salts, as several salts of sulphonic dyes are known to be insoluble at modest concentrations (3). However, apart from precipitation as the salt, the hydrophilic nature of the notified chemical should limit the affinity for soil and sediment. Thus the dye should remain mainly in the aquatic environment and accumulation in sediment is unlikely.

The chemical is unlikely to bioaccumulate due to its very low water partition coefficient, low fat solubility and high water solubility.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Nylosan Yellow E-2RL SGR

Test	Species	Outcome	Reference
Oral Toxicity	Rat	LD_{50} > 5000 mg/kg	(4)
Dermal Toxicity	Rat	LD_{50} > 2000 mg/kg	(5)
Skin irritation	Rabbit	Slight irritant	(6)
Eye irritation	Rabbit	Slight irritant	(7)
Skin sensitisation	Rabbit	Sensitiser	(8)

9.1.1 Oral Toxicity (4)

This study was performed in accordance with OECD Guideline No. 401 (9).

Albino Wistar rats (5/sex) were given C. I. Acid Yellow 256 by oral gavage at a dose of 5000 mg/kg. The vehicle was distilled water. Animals were observed for 14 days and then sacrificed. Macroscopic observations were performed.

No mortalities occurred during the study. No clinical signs were observed apart from brown/orange discolouration of faeces and urine. Body weight gains were unaffected by treatment. No macroscopic abnormalities were observed.

It can be concluded that the oral LD_{50} for C. I. Acid Yellow 256 in rats is > 5000 mg/kg.

9.1.2 Dermal Toxicity (5)

This study was performed in accordance with OECD Guideline No. 402 (10).

C. I. Acid Yellow 256 was administered by dermal application at a dose of 2000 mg/kg. The vehicle used was distilled water. Animals were observed for 14 days and then sacrificed. Macroscopic observations were performed.

No mortalities occurred during the study. No clinical signs were observed. Body weight gains were considered to be similar to that expected of untreated animals.

Erythema was observed on the treated skin of 2 males and 1 female.

No macroscopic abnormalities were observed.

It can be concluded that the dermal LD_{50} for C. I. Acid Yellow 256 in rats is > 5000 mg/kg.

9.1.3 Skin Irritation (6)

This study was performed in accordance with OECD Guideline No. 404 (11).

C. I. Acid Yellow 256 was applied onto the shaved intact dorsal skin of three female NZ White albino rabbits and covered with semi-occlusive dressing for 4 hours. The skin was observed for 72 hour after the removal of dressing. Skin irritation was scored according to the method of Draize (12).

No mortalities or clinical signs occurred during the study.

Skin irritation observed consisted of very slight erythema (primary irritation score = 1 in all three animals) and very slight oedema (primary irritation score = 1 in one animal). These had resolved by 24 hours in all animals except one in which erythema resolved by 48 hours. There was no evidence of a corrosive effect.

It can be concluded that C. I. Acid Yellow 256 is a slight skin irritant in rabbits.

9.1.4 Eye Irritation (7)

This study was performed in accordance with OECD Guideline No. 405 (13).

C. I. Acid Yellow 256 was instilled in the conjunctival sac of one eye of three female NZ White albino rabbits at a dose of 40 mg/animal. The other eye remained untreated. Eyes were observed for up to 7 days after instillation. Eye irritation was scored according to the method of Draize (12).

No mortalities were noted in the study. No clinical signs or systemic toxicity were observed during the study.

Adverse effects were observed on the iris of one animal which had resolved by 24 h and the conjunctivae of all three animals, which had resolved by 72 h in all animals. No corrosive effects were observed.

It can be concluded that C. I. Acid Yellow 256 is a slight skin irritant in rabbits.

9.1.5 Skin Sensitisation (8)

This study was performed in accordance with OECD Guideline No. 406 (14). The test used was the Magnusson and Kligman test (15) in the Himalayan albino guinea-pig.

Induction

On day 1, 20 guinea-pigs were injected intradermally on the clipped dorsal skin of the scapular region as follows: A) C. I. Acid Yellow 256, 5% w/v, in physiological saline; B) a 1:1 mixture of FCA and distilled water, and C) 10% w/v C. I. Acid Yellow 256 in a 1:1 (v/v) mixture of FCA and distilled water. On day 7, the clipped test area was treated with 10% sodium-dodecyl-sulphate (SDS) in vaseline. On day 8, the scapular region was treated again, with a 2 x 4 cm patch saturated with C. I. Acid Yellow 256 (50% w/w in vaseline) applied over the injection sites and covered with dressing for 48 hours. Skin reactions were assessed immediately after removal of dressing. Controls were treated identically to test animals with the omission of test substance.

Nineteen test animals showed slight erythema after removal of the patch, as did 8/10 control animals. This may have been due to the SDS treatment. No oedema was present.

Challenge

Test and control animals were challenged two weeks after the epidermal application ie. on day 22. Test substance at concentrations of 50%, 25% and 10% and vaseline vehicle alone was applied to clipped and shaved flanks of each guinea-pig, and occluded with dressing for 24 hours. Skin sensitisation was assessed 24 and 48 hours after removal of dressing.

Eighteen, seventeen and eighteen animals showed a skin reaction in response to the 50%, 25% and 10% test substance concentrations, respectively. These reactions consisted of redness, swelling and/or scaliness.

Sensitisation rates in the challenge test were 10%, 10% and 90% for the 50%, 25% and 10% concentrations, respectively. Positive responses in control animals challenged with the 50% and 25% concentrations made determinations of the sensitisation rates inconclusive.

It can be concluded that C. I. Acid Yellow 256 is a skin sensitiser in guinea-pigs.

Other Results

No symptoms of systemic toxicity and no mortalities were observed in this study.

9.2 Repeated Dose Toxicity

28-Day Oral Toxicity Study in Rats (16)

This study was performed in accordance with OECD Guideline No. 407 (17).

C. I. Acid Yellow 256 was administered orally to Wistar rats (5/sex/group) at doses of 0, 50, 200 or 1000 mg/kg/day for 28 days. The vehicle used was distilled water. All these animals were necropsied on day 28. The control and high dose (HD) groups contained 5 additional animals per sex for the recovery period.

At the lowest dose of 50 mg/kg/day, no treatment-related changes were observed.

At 200 mg/kg/day the following observations were made:

a) decreased haemoglobin and haematocrit values in females at week 4,
b) increased liver:body weight ratios in males at week 4 and
c) microscopically increased extramedullary haemopoeisis in males and females and increased haemosiderin deposits in females after week 4.

In the HD group the following observations were noted:

a) reduced body weight gains over the 6 week period,
b) anaemia characterised by decreased red blood cell count, haemoglobin and haematocrit and increased red cell distribution width (RDW) in both sexes, with increased mean corpuscular haemoglobin in females only; after the recovery period RDW remained increased in males only;
c) after 4 weeks increased serum levels of phosphate and albumin in both sexes and increased cholesterol and total protein in females, after the recovery period albumin and total protein remained elevated in females only;
d) increased relative liver and spleen weights (relative to the body weight) in both sexes, with relative liver weights still elevated in females after the recovery period, and
e) microscopically increased extramedullary haemopoeisis and haemosiderin deposits in the spleen of both sexes after week 4, which remained elevated in males only at the end of the recovery period.

At doses 200 mg/kg and above, C. I. Acid Yellow 256 produced anaemia. It can be concluded that the main target organ for toxicity is the blood.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (18)

This study was performed in accordance with OECD Guideline No. 471 (19).

The assay was performed in two independent experiments, using identical procedures, both with and without metabolic activation using S9 mix and S9 mix substitution buffer. Each concentration, including the controls, was tested in triplicate. C. I. Acid Yellow 256 was tested at concentrations of 10.0, 33.3, 100.0, 333.3, 1000.0 and 5000.0 μg/plate. No toxic effects were observed and background growth was not affected up to 5000

µg/plate, in either the presence or absence of metabolic activation in experiments. Up to the highest investigated dose a significant and reproducible increase of the number of revertants was not found in any strain compared to the solvent control.

The appropriate reference mutagens gave the appropriate positive responses.

In conclusion, C. I. Acid Yellow 256 did not induce point mutations by base pair changes or frameshifts in the genomes of the strains used.

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (20)

This study was performed in accordance with OECD Guideline No. 474 (21).

Three groups of NMRI mice (5/sex/group) were given a single dose of 5000 mg/kg C. I. Acid Yellow 256 (20 mL/kg in distilled water). Control animals were given the vehicle alone. Bone marrow cells were collected from each group at either 24, 48 or 72 hours after treatment. The reference mutagen cyclophosphamide was used as a positive control.

One thousand polychromatic erythrocytes (PCEs) per animal were scored for micronuclei. Cytotoxic effects were described by the ratio between polychromatic and normochromatic (NCEs) and reported as the number of NCE per 1000 PCE

At the dose used, the animals showed slight toxic reactions (reduced spontaneous activity, apathy, closed eyelids). The mean number of NCEs was not increased after treatment with C. I. Acid Yellow 256 compared to solvent control.

There was no enhancement in the frequency of the detected micronuclei at any preparation interval after treatment with C. I. Acid Yellow 256, compared to the solvent control.

It can be concluded that C.I. Acid Yellow 256 is not clastogenic in mice.

9.4 Overall Assessment of Toxicological Data

Animal studies indicate that C. I. Acid Yellow 256 has low acute oral and dermal toxicity (rat LD_{50}s > 5000 mg/kg and 2000 mg/kg, respectively). It had slight skin and eye irritating properties in rabbits and was a skin sensitiser in guinea-pigs. After 28 days of oral administration of C. I. Acid Yellow 256 to rats the main target organ of toxicity was the blood at doses ≥ 200 mg/kg/day.

Genotoxicity studies indicated that the notified chemical was not mutagenic in the *Salmonella typhimurium* reverse mutation assay and was not clastogenic in the mouse micronucleus test. As there was no positive effects *in vivo*, C. I. Acid Yellow 256 could not be classified as mutagenic.

On the basis of the submitted data, C. I. Acid Yellow 256 is classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (22) in relation to Sensitising effects (skin).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No environmental effects studies are required under the *Act* for notified chemicals of low volume. However, the following studies have been provided by the notifier.

Test	Material	Species	Result
Acute toxicity EEC C.1	Yellow E-JD 3442	Zebra-fish	96h LC_{50} > 1000 mg/L
Acute toxicity EEC C.2	Yellow E-JD 3442	Daphnia magna	48h EC_{50} > 1000 mg/L
Inhibition OECD TG 209	Yellow E-JD 3442	Bacteria from aerobic wastewater	3h IC_{50} = 88.5 mg/L

The above results indicate that Yellow E-JD 3442 is practically non-toxic to fish and daphnia and slightly toxic to aerobic wastewater bacteria.

The above tests were performed in accordance with standard EEC test methods or OECD test guidelines, and at facilities complying with OECD principles of GLP.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

As indicated above, the notifier states that 95% of the dye is fixed in the dyeing process, 5% of the dye used could be discharged into effluent of the dye houses where it is used. The notifier has calculated the concentration of discharge for a typical dye house. The calculations presented by the notifier are based o batch size of 100 kg of fabric and are as follows:

Use of C. I. Acid Yellow 256 per batch	= 1 kg
Amount of dye used per batch (61% active)	= 0.61 kg
Fixation rate of 95% , quantity passing to effluent	= 0.03 kg
Total volume of wash waters	= 7500 L
Effluent concentration from dye bath	= 4 ppm

The notifier claims there will be further dilution in the waste water treatment plant of the dye house; a dilution of 1 in 10 is not unrealistic, therefore dye lost to the sewerage system is estimated to be < 1 ppm for the above process.

It should be noted the above assumptions are very conservative, for example dilution in the dye house effluent is normally considered ten times greater. The EPA has therefore extended this calculation from the dye house. City based dye houses would have their effluent diluted in at least 100 times more water than the country locations.

- Dilution in sewage treatment plants for:

Rural treatment plant 5 ML per day	= 0.8 ppm
City treatment plant 500 ML per day	= 8 ppb

- In final receiving waters:

Inland waterway (1: 3 dilution)	= 0.27 ppm
City ocean release	< 1 ppb

These calculations are based on no removal of the notified chemical through adsorption to sludge the sewage treatment plant [unlikely due to its high water solubility (14 g/L) and low partition coefficient (log P_{ow} = -1.7)]. The calculations give expected environmental concentrations significantly below the LC_{50} for fish and daphnia. Therefore, the notified chemical is unlikely to present a hazard to the environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

In common with a number of other reactive dyes, the notified chemical is likely to be a skin sensitiser in humans and should be considered a potential respiratory sensitiser. It may cause slight skin and eye irritation and has the potential to cause anaemia on repeated or prolonged exposure but is not expected to be acutely toxic on ingestion or dermal exposure.

The notified chemical is imported as fine granules which are stated to be non-dusting. This suggests that inhalational exposure is unlikely to occur.

When the dye is in aqueous solution, skin contact is possible. However, transfer from the premix tank where the dye is dissolved to the dyebath is by pump or gravity feed. Thus the potential for spillage or splashing appears to be controlled.

Most dyebaths using the notified chemical are closed systems although there are open dyebaths in some dyehouses.

Although the notified chemical should be regarded as a potential respiratory sensitiser, the risk of respiratory sensitisation would appear to be low given that the dye is in a non-dusting form and is used in relatively small amounts. There is clearly a risk of skin sensitisation from contact with the dye in solution and personal protective equipment as outlined below should be used.

The public will not be exposed to C. I. Acid Yellow 256 during its importation and application to textiles by commercial dye houses. The public may be exposed to the fixed dye, at an estimated level of 0.57% of the weight of the fabric, in retail clothing fabric. Since the notified chemical will be chemically bound to textile fibres, has low potential for dermal absorption and toxicity studies submited indicated that it is of low toxicity, the notified chemical is unlikely to constitute a hazard to public health. The main hazard potential is skin sensitisation; however, the risk should be negligible due to the fixing of the dye to the fabric.

13. RECOMMENDATIONS

To minimise occupational exposure to C. I. Acid Yellow 256 the following guidelines and precautions should be observed:

. good general and local exhaust ventilation should be provided in weighing areas;

. particular care should be taken to avoid spillage or splashing of the dye solution;

. production of mists in the workplace during mixing operations should be avoided;

. good personal hygeine should be practiced to minimise the potential for ingestion;

. when handling the dye, dye solutions or textiles containing unfixed dye residues, personal protective equipment which conforms to and is used in accordance with Australian Standards (AS) for eye protection (AS 1336, AS 1337) (23,24), impermeable gloves (AS 2161) (25) and, if there is any possibility of dust generation, respiratory protection (AS 1715 and AS 1716) (26,27), should be worn. Overalls also should be worn;

. A copy of the Material Safety Data Sheet (MSDS) should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for C. I. Acid Yellow 256 was provided in Worksafe Australia format (28).

This MSDS was provided by Sandoz Australia Pty. Ltd. as part of their notification statement. The accuracy of this information remains the responsibility of Sandoz Australia Pty. Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of C. I. Acid Yellow 256 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

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