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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

CARTASOL BRILLIANT YELLOW K-6G

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

CARTASOL BRILLIANT YELLOW K-6G

1. IMPORTER

Sandoz Australia Pty. Ltd., 675-685 Warrigal Road, Chadstone, Victoria 3148.

2. IDENTITY OF CHEMICAL

Chemical Abstract Service Registry Number (CAS No): Not available

Trade name: CARTASOL BRILLIANT YELLOW K-6G

Other name/s: CARTASOL BRILLANTGELB K-6G; RWa 3904; CARTASOL BRILLANTGELB K-6G KONZ. LACTAT; CARTASOL BRILLANTGELB K-RWa 3904 fluessig; CARTASOL BRILLANTGELB K-RWa 3904P

3. PHYSICAL AND CHEMICAL PROPERTIES

At room temperature and atmospheric pressure, Cartasol Brilliant Yellow K-6G is an orange/yellow powder with no discernible odour. Its physical and chemical properties include:

Melting point: decomposition occurs at 80^{O}C before the melting point is reached

Density: 1.212 x 10^3 kg/m^3 (at 24^{O}C)

Vapour pressure: 63 $\pm$ 4 Pa (at 25^{O}C)

Water solubility: 395 g/L (at 25^{O}C)

Hydrolysis: not hydrolysed between pH 3.5-9.5 at <60^{O}C

Partition co-efficient:	log Po/w = -0.76 (at 19^{O}C)
Fat solubility:	0.078 g/kg (at 37^{O}C)
Surface tension:	70.1 mN/m (at 18^{O}C and 1.03 g/L)
Particle size:	7% of particles have particle size of <10 µm
Flammability:	combustible
Auto-ignition temperature:	not autoignitable
Explosion potential:	non-explosive
Reactivity:	stable at room temperature and atmospheric pressure; non-oxidising

Comments on physico-chemical data

Adsorption/desorption:	Test not performed but the dye is said to bind strongly to such materials such as calcium carbonate, aluminium silicate and magnesium silicate during dyeing operations. The notifier states that the dye is readily adsorbed onto clay, soil, organic humus and similar land fill materials. Such behaviour is consistent with the structure of the dye.
Dissociation constant:	No data were provided but ready dissociation in aqueous solution is indicated by the high water solubility and presence of quaternary ammonium centres.

Cartasol Brilliant Yellow K-6G will be imported as a 10.3% yellow aqueous solution. The aqueous solution has low volatility and no discernible odour.

4. PURITY OF THE CHEMICAL

Degree of purity: >60% w/w
(powder form)

Toxic or hazardous impurities: amines 0.02% w/w
(powder form) (predominantly aliphatic amines)

Additives/ adjuvants:

No additives/ adjuvants are present in the powder form.

The liquid form (as imported) is an aqueous solution which contains 2% w/w acetic acid (CAS No: 64-19-7) as additive.

5. INDUSTRIAL USE

Cartasol Brilliant Yellow K-6G will be imported for use solely as a dyestuff for the colouration of paper and leather. The anticipated usage of this chemical is 100-800 kg per year in the first five years. The maximum use in each tannery is not expected to exceed 50 kg/ year.

6. OCCUPATIONAL EXPOSURE

Cartasol Brilliant Yellow K-6G will be imported and used in the liquid-form, therefore, dermal exposure will be the main route of worker exposure. Exposure through inhalation is unlikely as the vapour pressure of Cartasol Brilliant Yellow K-6G is low as it is a solid with a high molecular weight. It is anticipated that the high vapour pressure mentioned in Section 3 of this report is due to the presence of water at a concentration of approximately 4% w/w.

The notifier states that Cartasol Brilliant Yellow K-6G will be imported and stored in 800-1000 L metal-sheathed plastic Schutz containers. It will be repacked into 20-25 L plastic containers for distribution to users of the dyestuff. It is therefore anticipated that significant risk of exposure from accidental spillage during storage and transit is unlikely.

Repacking of the dyestuff into smaller plastic containers will be conducted at Sandoz, Moorabbin, Victoria. The chemical will be run off from the bottom outlet cock of the 800-1000 L mini-bulk containers in which it will be imported, into the 20-25 L plastic containers. Two process workers in charge of this operation may come into direct contact with this chemical if personal protection measures and good work practices are not implemented.

Papermill and tannery workers involved with dosing the dyestuff into the machines may also come into direct contact with this chemical if personal protection and good work practices are not implemented. Nine to 20 of such workers may be exposed.

In addition to the above, tannery workers involved with the handling of the wet, dyed leather may also come into direct contact with this chemical if personal protection measures are not implemented. Up to eight such workers may be exposed to the dyestuff during this process.

The notifier states that once the paper or leather is dried, the dyestuff is chemically bound to these materials thus presenting no risk of exposure to workers. It is therefore anticipated that the exposure of the handlers and end-users of these dried materials to the dyestuff will be extremely low.

7. PUBLIC EXPOSURE

Cartasol Brilliant Yellow K-6G in liquid-form will be imported for industrial use only and as this chemical will be firmly bound to paper and leather after use, and disposal will be by landfill, the potential for public exposure to this chemical is expected to be low.

8. ENVIRONMENTAL EXPOSURE

. Release

In the repacking operation at Sandoz, Moorabbin, Victoria, hoses used for the transfer of the chemical will be flushed to sewer (100 g of dyestuff per batch, or 0.6-0.8 kg per annum) and container residues (0.5 kg per batch, or 3-4 kg per annum) will be consigned with the container to landfill.

Basic dyes are known to be bound through strong and rapid ionic interactions between the cationic centres on the dyestuff and acidic sites, mostly carboxylate groups on the fibres (1). The notifier states that after dyeing, aproximately 95% of the dyestuff will be bound to the substrate with the remaining dyestuff (up to 5%) being bound to suspended cellulose fines and fillers which pass out with the waste water to effluent treatment plants. These suspended materials will be extracted during waste water treatment and consigned to landfill with sludge. It is expected that each of the three paper mills using the dyestuff will run for four days per month and will dispose of 2.1 kg of the dyestuff with sludge to landfill from a monthly budget of 400 kg liquid dyestuff (41 kg of the notified chemical). The amount of unfixed dyestuff remaining in solution in the waste water is said to be a minute fraction of that disposed with the sludge.

The notifier notes that possibly up to three tanneries may also use the dyestuff, with a maximum use at each site of not greater than 50 kg per year. Tanneries are expected to use 2.5 kg of the dyestuff per batch of leather, of which no more than 0.1 kg will be disposed of with the sludge. Sandoz estimates that a maximum of 1-2 kg will be disposed of to landfill from each tannery annually, but provides no further details.

. **Fate**

The bulk of the dyestuff will be bound to paper or leather and in this state is not expected to impact on the environment.

While the dyestuff is water soluble, its cationic nature results in removal from solution through binding to suspended particles and dissolved organic matter. Residues which escape binding to the paper or leather substrates will be sent to landfill bound to fibre or mineral fillers as part of a sludge, where they can be expected to remain immobile.

The amount of dyestuff which will remain in solution and be discharged with waste water is said to be extremely small. Dissolved concentrations following passage through effluent treatment works are expected to be very small as tests to mimic the mixing of dyestuff wastes with the biomass in an activated sludge plant indicate that basic dyes are highly adsorbed (2).

Accumulation of residues in the aquatic environment is not expected as the dyestuff has high solubility and returned moderate result for ready biodegradability (30% loss of dissolved organic carbon in 28 days)(3). The biodegradability test was carried out in accordance with *OECD Guidelines for Testing of Chemicals No: 301E* (4).

9. ASSESSMENT OF TOXICOLOGY DATA

9.1 Acute Toxicity

Table 1 Summary of acute toxicity of Cartasol Brilliant Yellow K-6G

Test	Species	Outcome	Reference
Oral	Rat	LD_{50}: >5000 mg/kg	5
	Rat	LD_{50}: >2000 mg/kg	6
	Rabbit	non-irritant	7
Eye irritation	Rabbit	slight irritant	8
Skin sensitisation	Guinea Pig	weakly sensitising	9

9.1.1 Oral toxicity (5)

This study was carried out in accordance with the *OECD Guidelines for Testing of Chemicals* No: 401 (10).

Cartasol Brilliant Yellow K-6G in water was administered by a single gavage to a group of 10 (five males and five females) albino *Wistar (outbred, SPF-Quality)* rats at a dose level of 5000 mg/kg. The animals were observed for 15 days. No deaths occurred during the study. All animals produced dark

yellow/orange urine from Day 3-6. This was due to the excretion of the test substance or its metabolites in the urine. No treatment related signs of toxicity were observed. Gain in bodyweight was unaffected. Necropsy revealed no macroscopic changes.

Results of this study indicate an acute oral LD_{50} of >5000 mg/kg in rats of both sexes for Cartasol Brilliant Yellow K-6G.

9.1.2 Dermal toxicity (6)

This study was carried out in accordance with the *OECD Guidelines for Testing of Chemicals* No: 402 (11).

A single dose of 2000 mg/kg of Cartasol Brilliant Yellow K-6G moistened with water was applied by occlusive application to the shaved backs of 10 (five males and five females) albino *Wistar (outbred, SPF-Quality)* rats. Twenty-four hours post-exposure, the dressings were removed and the skin reactions assessed. The animals were observed for 15 days. No deaths occurred during the study. There was no treatment related toxicity. No skin reactions were observed, however, all animals showed yellow/ green discolouration of the application site by the dyestuff from Day 5 till the end of the study period. It should be noted that the yellow discolouration by the dyestuff could hinder the observation of erythema but the effect would have to be slight for it to be masked. Gain in bodyweight was unaffected. Necropsy revealed no macroscopic changes.

Results from this study indicate an acute dermal LD_{50} of >2000 mg/kg in rats of both sexes for Cartasol Brilliant Yellow K-6G.

9.1.3 Skin irritation (7)

This study was carried out in accordance with the *OECD Guidelines for Testing of Chemicals* No: 404 (12).

A single dose of 0.5 g of Cartasol Brilliant Yellow K-6G moistened with water was applied by occlusive application to the shaved flanks of three female *New Zealand White (SPF-Quality)* rabbits. Four hours post-exposure, the dressings were removed and the skin reaction assessed according to the scoring system

described in (11) at 1, 24, 48 and 72 hours after the removal of the dressing. Apart from a transient yellow discolouration of the application site by the dyestuff at one hour post-exposure, no skin reactions were observed. It should be noted that the yellow discolouration by the dyestuff could hinder the observation of erythema but the effect would have to be slight for it to be masked. No deaths occurred during the study and no treatment related toxicity was observed. Necropsy was not performed on any of these animals.

The results from this study indicate that Cartasol Brilliant Yellow K-6G is not a skin irritant in rabbits at the concentration tested.

9.1.4 Eye irritation (8)

This study was carried out in accordance with the *OECD Guidelines for Testing of Chemicals* No: 405 (13).

A single dose of 65 $\pm$ 2 mg of Cartasol Brilliant Yellow K-6G was instilled in the conjunctival sac of the left eye of each of three female *New Zealand White (SPF-Quality)* rabbits. The right eye remained untreated and served as the control. The eyes were examined 1, 24, 48 and 72 hours post-exposure, and thereafter at 7, 14 and 21 days after the instillation of the test substance. Treatment of the eye with fluorescein 24 hours after instillation of the test substance revealed no corneal epithelial damage in any of the animals. Yellow staining of the eyelashes by the dyestuff was observed in all three animals 24 hours after exposure. Irritation was scored according to the scoring system described in (13). Hyperaemic to diffuse beefy red colour and slight to obvious swelling of the conjunctivae, were observed in all three treated eyes. In two animals, chemosis resolved within 21 days of exposure. The redness persisted in all three animals during the entire study period. All three animals showed some lacrimation and discharge on the first three days of the study and in one animal this effect lasted till Day 7. No deaths were noted during the study and no systemic toxicity was evident.

The results of this study indicate that in accordance with Draize (14), Cartasol Brilliant Yellow K-6G is slightly irritating to the rabbit eye.

9.1.5 **Skin sensitisation (9)**

This study was carried out in accordance with the *OECD Guidelines for Testing of Chemicals* No: 406 (15).

The Guinea Pig Maximisation Test (16) was used. Skin reactions were assessed according to the scoring systems described in (9). Formaldehyde was used as the positive control and water was used as the negative control.

In the positive control group, 20 guinea pigs (species and sex unspecified) were intradermally induced with a 1% w/w solution of formaldehyde in physiological saline followed by an epidermal induction with a 1% w/w solution of formaldehyde in water. For the epidermal challenge, three dilutions of formaldehyde in water at concentrations of 0.5, 0.25 and 0.1% w/w were used. Erythema was observed in 90% of the animals tested.

Preliminary study

In the preliminary study, five *Dunkin-Hartley* albino guinea pigs were used. Four intradermal injections were made into the clipped shoulder region of one guinea-pig using a 5% w/w concentration of Cartasol Brilliant Yellow K-6G in water. Twenty-four hours post-exposure, the skin reaction were assessed. Erythema and necrosis were observed. The same animal was later subjected to occlusive epidermal administration of Cartasol Brilliant Yellow K-6G at a concentration of 25% w/w for 24 hours. Erythema was observed at 24 hours and 48 hours after the removal of the dressing but no treatment-related systemic signs of toxicity were observed.

The remaining four animals were epidermally dosed with aqueous solutions of Cartasol Brilliant Yellow K-6G at concentrations of 5, 10 and 25 % w/w for 24 hours. Slight to well-defined erythema was observed with the 10 and 25% w/w solutions, 24 hours after removal of the dressings but these animals had recovered at 48 hours. No skin reactions were noted with the 5% w/w solution.

Main study

In the induction and challenge study, 30 female *Dunkin-Hartley* albino guinea pigs were used of which 10 served as negative controls.

Induction

The 20 test animals were each induced by intradermal injections of a 2.5% w/w solution of Cartasol Brilliant Yellow K-6G in physiological saline and a 5% w/w solution in Freunds' Complete Adjuvant at the scapular region. One week later, these animals were subjected to occlusive epidermal application of a 25% w/w aqueous solution of the test substance for 48 hours. Animals in the negative control group were treated in the same manner as the test animals but with the omission of the test substance. Erythema and oedema were not observed in either the test or negative control group. However, the yellow discolouration of the application site by the dye could hinder the observation of erythema but the effect would have to be slight for it to be masked.

Challenge

Two weeks following the epidermal induction application, each animal in both groups was challenged with the occlusive epidermal application of an aqueous solution of Cartasol Brilliant Yellow K-6G at concentrations of 2.5, 5 and 10% w/w. The animals were exposed for 24 hours. The application sites were assessed for erythema and oedema 24 and 48 hours after the removal of the dressing, using a modified scoring system (17). One animal from the 10% w/w test group was found to be sensitised as indicated by moderate but confluent redness of the skin which was not observed in the controls. No deaths occured during the study and gain in bodyweight was unaffected.

Results form this study indicate that Cartasol Brilliant Yellow K-6G is weakly sensitising in the guinea pig.

9.2 Short-term 28-day repeated dose oral toxicity (18)

This study was carried out in accordance with the *OECD Guidelines for Testing of Chemicals* No: 407 (19).

Cartasol Brilliant Yellow K-6G in water was administered by gavage once daily to groups of five male and five female *Sprague-Dawley CD SPF-Quality* rats at dose levels of 0 mg/kg (control, 10 rats), 50 mg/kg (10 rats), 200 mg/kg (10 rats) and 1000 mg/kg (10 rats) for 28 days. No deaths were noted during the study. A slight decrease in bodyweight was observed in both males and females at all dose levels when compared with the control but this was not statistically significant. Food consumption was not affected. No treatment related clinical signs of toxicity were observed. No ophthalmoscopic abnormalities were observed. Haemotological and biochemical data showed no changes of toxicological significance. Statistically significant increases in testes weight (low and intermediate dose level), and liver weight to body weight ratio (high dose level) were noted in males but a dose-relationship was not observed. No macroscopic or microscopic changes were noted at necropsy.

Results from this study indicate that Cartasol Brilliant Yellow K-6G has no significant toxicological effects in rats at the dose levels tested.

9.3 Genotoxicity

Table 2. Summary of genotoxicity of Cartasol Brilliant Yellow K-6G

Test	Dose range	Outcome	Reference
Salmonella typhimurium ReverseAssay 20	10 - 5000 µg/plate	negative	
in-vivo mouse assay 21	3000 mg/kg	negative	

9.3.1 Salmonella typhimurium reverse mutation assay (20)

This study was carried out in accordance with the *OECD Guidelines for Testing of Chemicals* No: 471 (22).

Cartasol Brilliant Yellow K-6G at concentrations of 10.0, 100.0, 333.3, 1000.0 and 5000.0 µg/plate was tested in two independent experiments for gene mutation according to the direct plate incorporation method using *Salmonella typhimurium* strains TA 1535, TA 1537, TA 98 and TA 100, both in the presence and absence of microsomal activation. Untreated and solvent (water) treated strains were used as negative controls. Positive controls used were sodium azide, 4-nitro-o-phenylene-diamine and 2-aminoanthracene. No dose-related increase in the number of revertant colonies was observed in any of the strains exposed to Cartasol Brilliant Yellow K-6G both in the presence and absence of microsomal activation. In contrast, the positive controls showed marked increases in the number of revertant colonies.

The results of this study suggest that Cartasol Brilliant Yellow K-6G was not mutagenic under the experimental conditions reported.

9.3.2 Micronucleus assay in bone marrow cells of the mouse (21)

This study was carried out in accordance with the *OECD Guidelines for Testing of Chemicals* No: 474 (23).

Cartasol Brilliant Yellow K-6G in distilled water was administered orally in a single dose of 3000 mg/kg bodyweight to a group of 10 (five males and five females) *NMRI* mice. The negative control used was the solvent, distilled water. Cyclophosphamide was used as the positive control. The number of polychromatic cells with micronuclei in animals treated with Cartasol Brilliant Yellow K-6G were in the same range as the negative control; in contrast, the positive control showed a marked increase.

Results of this study suggest that Cartasol Brilliant Yellow K-6G was not genotoxic under the experimental conditions reported.

9.4 Overall assessment of toxicology data

Cartasol Brilliant Yellow K-6G has very low acute oral toxicity (oral LD_{50} in rats: >5000 mg/kg) and low acute dermal toxicity (dermal LD_{50} in rats: >2000 mg/kg). Animal tests show that Cartasol Brilliant Yellow K-6G is a slight eye irritant and a weak skin sensitiser but not a skin irritant. A short-term repeated dose study shows no effects in rats dosed by gavage at dose levels 50, 200 and 1000 mg/kg/day. Both the *Salmonella typhimurium* reverse mutation assay and the *in-vivo* mouse micronucleus assay suggest that Cartasol Brilliant Yellow K-6G is not genotoxic.

10. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Animal tests show that Cartasol Brilliant Yellow K-6G is a skin sensitiser and an eye irritant, therefore, if inhaled, it may irritate or sensitise the respiratory tract. As a result, inhalation, skin and eye contact should be prevented. The notifier states that no data on the effect of this chemical on human health have been reported from its use overseas. However, it should be noted that current experience with this chemical is limited since it was only introduced for use in 1989.

Cartasol Brilliant Yellow K-6G is stable at room temperature and pressure. It has low volatility, is highly soluble in water, does not sustain burning and has no explosive potential, therefore it should not pose any significant risk to the safety of workers in the work environment.

Due to the low public and occupational exposure under correct handling and dyeing procedures, it is unlikely that this chemical will pose any significant health and safety hazard to the public or workers.

11. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Table 3. Summary of ecotoxicity of Cartasol Brilliant Yellow K-6G

Test	Species	Outcome	Reference
96 hours acute	*Guppy (Poecilia reticulata)*	LC_{50}=5.6-10 mgL^{-1}	24
48 hours	*Daphnia magna*	EC_{50}=17.2 mgL^{-1}	25

The above results show the dye to be moderately toxic to fish and slightly toxic to daphnids, but should be regarded with some caution as static conditions and nominal concentrations were used. Analytical concentrations in the fish test were consistently lower by 30-80% than nominal, but no temporal trends were apparent. Aside from mortality, observed effects on fish at the lower end of the toxic range were discolouration and hypoactivity.

Quaternary ammonium compounds, if tested for fish toxicity in deionised water will, through ionic interactions, bind readily to gills. This can give rise to toxic effects due to reduction of oxygen transfer across damaged membranes or through effects on the ionic balance. However, the literature records that toxicity is greatly reduced in the environment because of preferential binding to dissolved organics in surface water (26).

The influence of Cartasol Brilliant Yellow K-6G on oxygen consumption of activated sludge (27) was tested according to *OECD Guidelines for Testing of Chemicals No: 209* (28). Respiratory inhibition was moderate (approximately 25%) below 100 mgL^{-1}, and the test returned an IC_{50} in excess of this concentration.

12. ASSESSMENT OF ENVIRONMENTAL HAZARD

The cationic nature of Cartasol Brilliant Yellow K-6G entails its ready removal from solution by binding to organic matter. The proposed level of importation ensures a low environmental exposure to the free dyestuff.

The dyestuff is not expected to impact on the environment when bound to paper or leather. In its free state, the dyestuff proved moderately toxic to fish in laboratory tests, but toxicity should be reduced by at least an order of magnitude in natural surface waters because of microbial degradation and preferential binding to dissolved organics.

As the notifier has not indicated where Cartasol Brilliant Yellow K-6G will be used, it is prudent to assume a small effluent stream. Assuming as a worst case that the residual dyestuff at a level of 5% of the total amount of dyestuff used, is discharged in 5 ML of effluent with no binding to suspended fibre and mineral fillers, the resulting concentration would be approximately 100 ppb (0.5 kg in 5×10^6 L). This is less than two orders of magnitude lower than concentrations which produced toxic effects on aquatic organisms in the laboratory, but adsorption to solids before discharge, and further dilution and reduced bioavailability in natural surface waters, should provide an acceptable margin of safety. Environmental concentrations resulting from formulation wastes would be expected to be even lower because of dilution by other waste streams entering the sewage treatment works and subsequent dilution by the receiving ocean. Accordingly, the environmental hazard appears low.

13. RECOMMENDATIONS FOR SAFETY PROCEDURES TO CONTROL OCCUPATIONAL EXPOSURE

To minimise occupational exposure to the formulated product containing the notified chemical, the following guidelines and precautions should be observed:

. suitable personal protective equipment which comply with Australian Standards (AS) should be worn such as:

  . safety glasses (AS 1337) - *Eye Protectors for Industrial Applications* (29);

  . impervious elbow length gloves (AS 2161) - *Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)* (30),

  . protective clothing; and

  . respirators (AS 1716) - *Respiratory Protective Devices* (31);

. enclosed systems should be used;

. good work practices should be implemented to avoid splashings or spillages;

. storage of the chemical in robust sealable containers is essential;

. good housekeeping and maintenance should be practised. Spillages should be cleaned up promptly using absorbents;

. personal hygiene should be observed;

. the workplace should be well ventilated with local exhaust ventilation to ensure that the exposure standard for acetic acid (TWA: 10 ppm) (32) is not exceeded;

a copy of the Material Safety Data Sheet (MSDSs) for the notified chemical and the formulated product should be easily accessible to employees.

14. RECOMMENDATIONS FOR MATERIAL SAFETY DATA SHEET (MSDS)

The MSDSs for the notified chemical (Attachment 1) and the formulated product (Attachment 2) have been compiled according to Worksafe Australia format (33).

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of Cartasol Brilliant Yellow K-6G shall be required by Sandoz Australia Pty. Ltd. if any circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

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