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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

1,4-Benzenediamine, N,N'-Mixed Phenyl and Tolyl and Xylyl Derivatives (Wingstay 200)

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Director
Chemicals Notification and Assessment

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(Wingstay 200)

1. APPLICANT

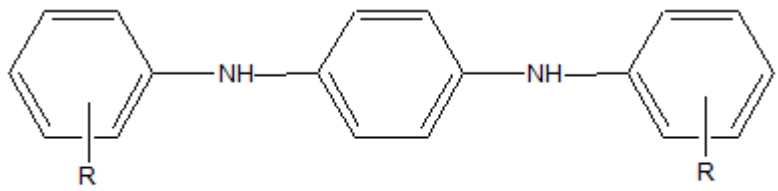
Quenos Australia Pty Ltd of 471-513 Kororoit Creek Road ALTONA VIC 3018 (ACN 054 196 771) has submitted a standard notification statement in support of their application for an assessment certificate for Wingstay 200.

2. IDENTITY OF THE CHEMICAL

The notifier did not apply any information on the notified chemical to be exempted from publication in the Full Public Report and the Summary Report.

Chemical Name:	1,4-Benzenediamine, N,N'-mixed phenyl and tolyl and xylyl derivatives.
Chemical Abstracts Service (CAS) Registry No.:	68953-83-3
Other Names:	Mixed diaryl-*p*-phenylenediamines Hydroquinone, *o*-toluidine, xylidine, aniline condensate
Marketing Name:	Wingstay 200
Molecular Formula:	The notified chemical is a complex reaction product.

Structural Formula:



R = H or CH_3

Molecular Weight: 302

Method of Detection and Determination:	High performance Liquid Chromatography (HPLC), Mass Spectrometry (MS) and UV.
Spectral Data:	Spectra were provided.

• Comments on Chemical Identity

The notified chemical is a complex reaction product and the structure given is representative only. The final product contains five major components that vary in the number and placement of methyl groups on the phenyl rings with multiple isomers existing for three of the components.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa:	Dark brown/black viscous liquid.
Boiling Point:	> 300 °C
Specific Gravity:	1.2
Vapour Pressure:	Not determined. Estimated to be $<1x10^{-8}$ kPa using Soave-Redlick-Kwong equation of state (SRK EOS).
Water Solubility:	1.02 mg/L at 20°C
Partition Co-efficient (n-octanol/water):	Log P_{OW} = 3.50 - 4.56
Hydrolysis as a Function of pH:	Not determined.
Adsorption/Desorption:	Not determined.
Dissociation Constant:	Not determined.
Particle Size:	Not applicable for a liquid.
Flash Point:	>93°C (estimated)
Flammability Limits:	Not determined.
Autoignition Temperature:	Not determined.
Explosive Properties:	The molecular structure of the notified chemical does not indicate an explosion hazard.
Reactivity/Stability:	The new chemical is a stable liquid. It is not considered reactive. The material does not degrade or decompose at ambient temperatures. Hazardous

polymerisation will not occur. However, it is recommended that the new product be kept away from excessive heat and open flame, as the material will burn.

3.1 Comments on Physico-Chemical Properties

The water solubility and partition coefficient tests were performed according to EEC/OECD test guidelines at facilities complying with OECD Principles of Good Laboratory Practice.

The boiling point of the new chemical was determined using Thermal Gravimetric Analysis. An analysis of the melting temperature was undertaken using Modulated Differential Scanning Calorimetry and the glass transition (Tg) was determined to be –12ºC.

The water solubility was determined using the column elution method with HPLC-UV detection (Mao, 1996).

Hydrolysis, as a function of pH, could not be determined due to the low solubility of the notified chemical in water. The chemical does not contain any groups likely to hydrolyse under environmental conditions, though the two aromatic amine groups may hydrolyse under severe pH conditions.

The Log Pow range was determined using the HPLC method (Mao, 1995) separately on the five major components of the chemical. Results are as follows:

Compound	***Pow***	***Log Pow***
R-59	3160	3.50
R-1679	8320	3.92
Dimethyl diphenyl-p-phenylenediamine	14800-16200	4.17-4.21
Trimethyl diphenyl-p-phenylenediamine	24500-26300	4.39-4.42
Tetramethyl diphenyl-p-phenylenediamine	32400-36300	4.51-4.56

These low values suggest a low tendency for the chemical to be associated with the aqueous phase.

A test for the adsorption/desorption was not performed, but the Log Pow value suggests that the chemical could be expected to show adsorption to soil and sediment. Further, the substance is a highly viscous ‘tar-like’ material that should physically become bound to the soil if spilt into the environment in its pure state. The low water solubility of the chemical supports that it may bind to soil.

The dissociation constant of the chemical has not been determined due to its low solubility. However, a dissociation constant study for N,N’-diphenyl-p-phenylenediamine (one of the

five major components of the notified chemical) performed by Hambrick (1994) under OECD TG 112 was submitted, which indicated that the pKa for the test material was <2.

4. PURITY OF THE CHEMICAL

Degree of Purity: > 99.9 %

Hazardous Impurities:

Chemical name:	*o*-toluidine
Synonyms:	Benzenamine, 2-methyl
CAS No.:	95-53-4
Weight percentage:	< 0.1 %
Toxic properties:	May cause cancer (category 2); Toxic by inhalation and if swallowed; Irritating to eyes; Very toxic to aquatic organisms (NOHSC, 1999a).

Non-hazardous Impurities (> 1% by weight): None.

Additives/Adjuvants: None.

5. USE, VOLUME AND FORMULATION

The notified chemical is used as an antioxidant in the manufacture of one grade of styrene-butadiene rubber (SBR). Its main role is to protect the rubber from ozone degradation.

The notified chemical will be imported into Australia under the name of Wingstay 200 in sealed 200 L steel drums. In Australia, Wingstay 200 will be used by the notifier in the manufacture of synthetic grade rubber at a maximum concentration of 0.75 % by weight. The anticipated import volume of the notified chemical is 1-10 tonnes per annum for the first 5 years.

The dried rubber will be sold in bales to customers to be mixed with other components and incorporated into rubber products, such as car and truck tyres and retreads at up to 20 g per tyre.

6. OCCUPATIONAL EXPOSURE

Transport and storage
Wingstay 200 is packaged in sealed 200 L steel drums. Two workers will receive the import at the dock and 1-2 workers will be involved in the transport of the product to the warehouse and manufacturing site.

Only in the event of accidental spillage would there likely to be exposure to the notified chemical.

Rubber block Manufacturing
The steel drums are first placed in a temperature-controlled room and heated to increase the flow rate. Operators will pump the heated notified chemical from drums to an intermediate storage tank. The notified chemical is metered out and transferred into a processing tank with other components for rubber production to given a final concentration of 0.75%. The notified chemical is incorporated into the rubber slurry and is subsequently bound in the polymer. Final processing includes separation of water from the rubber, drying of the rubber and squeezing of the rubber into bales of approximately 36 kg blocks prior to transfer to customers.

There will be 1-4 workers involved in the operation of the valves and pumps of the equipment. Service personnel maintaining the equipment may also come into contact with the notified chemical. The total number of workers potentially exposed is given as 10. Workers may be exposed to the notified chemical when manually inserting the transfer pump into the open bung hole of the 200 L drums. Dermal contact would be the main route for occupational exposure. Eye contamination could be possible. The intermediate storage tank and the processing tank are closed systems with adequate workplace ventilation including local exhaust ventilation. Rubber manufacture processes such as mixing ingredients, separating water, drying and squeezing, take place in an automated system with minimal potential for occupational exposure.

The notifier estimated that workers could be potential exposed to the notified chemical for approximately 10-15 minutes each time during the pumping operation. Approximately 8-10 drums will be used over a two-day period, twice a year. Personal protective equipment (PPE) recommended by the notifier includes suitable industrial clothing, footwear, vapour respirators, safety glasses and protective gloves.

At the end of rubber block manufacturing process, the notified chemical becomes encapsulated in solid rubber and bound to the polymer backbone of SBR 1500. It will remain in the rubber matrix and is not readily available biologically. However, the notified chemical will denature as a result of its interaction with air over time. Normal packaging of SBR 1500 is 42x36 kg bales in normal 1.5 MT returnable steel packs. Each bale is wrapped in polyethylene film to protect the rubber from contamination.

Rubber products manufacturing
At the rubber products manufacturing sites, the rubber blocks will be mixed with other ingredients in an enclosed vessel such as Banbury internal mixer at a batch size of 200-350 kg. The resulting mixed compound is then ready for extrusion or sheeting and assembly into such rubber products as tyres. The notifier indicated that the concentration of the notified chemical in end products is very low (up to 20 g per tyre).

7. PUBLIC EXPOSURE

At the end of manufacturing process, the notified chemical becomes a component of rubber tyres or retreads. It remains in the rubber matrix and is not readily available biologically. Negligible release of the notified chemical is expected from wear and tear of tyres during use,

given that its concentration in the end use product is very low and its antioxidant/antiozonant capacity is diminished and exhausted over time. Therefore, public accessibility and exposure to the notified chemical is considered to be low due to the end use pattern of the product.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Release to the environment may occur during the rubber manufacturing process and the reformulation of the rubber into the final products, tyres and retreads.

The environmental release resulting from the rubber manufacturing will result from residues remaining in the import drums after 'emptying' and chemical that may be dissolved in the effluent water from the 'squeezing' of the rubber crumbs during the drying process. The notifier estimates that 1.1% (up to 110 kg/annum) of the notified chemical would remain as residues in the drums and will be destroyed by incineration or disposed of to landfill by licensed drum reconditioners. Pumps and mixing vessels used specifically for rubber production are not cleaned between batches. It is claimed that virtually no release will result from spillages because the chemical has high viscosity and small spillages would be cleaned up and recycled or incinerated. The notifier has supplied details on the amount of chemical expected to be released in the plant effluent from 'squeezing' the rubber crumbs (see Assessment of Environmental Hazard for PEC calculation).

Rubber residues and spills from the tyre making process at the customer plants are to be reused in the next batch of product. No residue will remain in the wrapping on the rubber bales, spills will be cleaned up and reused where possible and equipment will not be cleaned between batches. It is claimed that the total waste from the reformulation process is <1% or up to 100 kg/annum of the notified chemical. There is no information on how this waste will be disposed, but landfill is the most likely disposal method and all of the chemical would be expected to remain bound within the solid rubber matrix.

The notifier claims that the new chemical will be used in the rubber that makes up the sidewall of the tyres but not the tread. However, they have supplied information on the release from tyre wear if the rubber containing the notified chemical should be used on the tread of the tyres. The tread component of the average tyre weighs 1.65 kg (Wingstay 200 present at <1% or 16.5 g/tyre) and the treadwear of the tyre is approximately 0.016 g/km of travel or 0.064 g/km for the 4 tyres on the motor vehicle. The notified chemical is expected to remain firmly bound in the inert rubber matrix of the tyre wear particles and to not leach from the vulcanized rubber network. A study on an analogous chemical Wingstay 100, showed that it was extractable from the final rubber product at 1.3% after 15 days of immersion in water at pH 4.

8.2 Fate

The fate of the notified chemical will be tied almost entirely to that of the rubber tyres in which it is incorporated. In all cases the chemical will remain strongly bound to the rubber matrix. Old tyres are used for diverse purposes. Many are burnt as fuel in kilns, some are shredded and used to make articles such as rubber bricks, some will be disposed of directly to landfill. During incineration of waste or used rubber articles the chemical will be destroyed

by conversion to oxides of carbon and nitrogen and water vapour. Chemical in rubber articles disposed of to landfill will remain bound to rubber and undergo slow degradation.

Ready biodegradability assessed using the CO_2 Evolution Test (Armitage, 1996) (OECD TG 301B) with sodium benzoate as the reference material showed 1.72% biodegradation for the test concentration after 28 days, limited by the water solubility of the chemical. The notified chemical is not readily biodegradable. As the test substance was still producing a small amount of CO_2 at the end of the study, further degradation is likely to occur over a longer period. The reference material showed 86.7% biodegradation at 10 mg/L concentration. The chemical was found not to significantly inhibit microbial activity. Although the notified chemical is not readily biodegradable, it should ultimately be degraded.

No bioconcentration data for Wingstay 200 were submitted, instead the notifier provided computer generated estimates for a closely related material, Wingstay 100. Wingstay 100 differs from the notified chemical only in that it has a lower degree of methyl substitution on the aryl rings. The computer generated data (McLaren-Hart, 1998) indicated a BCF for Wingstay 100 of 1000-7000, indicating that this material is highly bioconcentrating (Mensink et al, 1995). Similarly, the values for Log Pow (3.5-4.6) and water solubility (1 mg/L) of Wingstay 200 indicate significant potential for bioconcentration (Connell, 1989).

Small amounts of the notified chemical (0.72 μg/L – see Assessment of Environmental Hazard) entering the waste water during the manufacturing process are likely to adsorb to sludge.

9. EVALUATION OF TOXICOLOGICAL DATA

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

The *in vivo* micronucleus assay in the bone marrow cells of mouse was performed on Wingstay 100, which has a similar chemical structure with Wingstay 200 except a lower degree of methyl substitution on the aryl rings. The test report is accepted as analogue data in this notification.

9.1 Acute Toxicity

Summary of the acute toxicity of Wingstay 200

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	2 000 mg/kg<LD_{50}<5 000 mg/kg	Merriman, 1995a
acute dermal toxicity	rabbit	LD_{50}>2 000 mg/kg	Merriman, 1995b
acute inhalation toxicity		Not provided.	
skin irritation	rabbit	A slight irritant	Merriman, 1995c
eye irritation		Not provided.	
skin sensitisation	guinea pig	A skin sensitiser	Merriman, 1995d

9.1.1 Oral Toxicity (Merriman, 1995a)

Species/strain: Rats/Sprague-Dawley

Number/sex of animals: 5/sex/dose

Observation period: 14 days.

Method of administration: Oral doses of 2000 and 5 000 mg/kg (vehicle: corn oil) were given by gavage.

Test method: OECD TG 401

Mortality:

Dose (mg/kg)	*Male*	*Female*
2 000	0/5	0/5
5 000	5/5	5/5

Clinical observations: All mortality occurred by day 4. Notable abnormalities in rats at 5 000 mg/kg included decreased activity, wobbly gait, prostration, apparent hypothermia, decreased defecation, piloerection, fecal/urine staining, lacrimation, abnormal breathing, dilated pupils and dark material around the facial area.

Clinical observations in rats at 2 000 mg/kg were limited to rough hair coat, fecal/urine staining and dark material around the facial area.

Morphological findings: Dead animals had abnormal contents in the digestive tract, thymus with dark red foci and reddened mucosa in the stomach.

No gross abnormalities were observed in survived rats.

Comment: None.

LD_{50}: Between 2 000 and 5 000 mg/kg.

Result: The notified chemical was of very low acute oral toxicity in rats.

9.1.2 Dermal Toxicity (Merriman, 1995b)

Species/strain: Rabbits/New Zealand White

Number/sex of animals: 5/sex

Observation period: 14 days.

Method of administration: The notified chemical (2 000 mg/kg) was applied to 10% of the body surface area under an occlusive dressing for 24 hours.

Test method: OECD TG 402

Mortality: None.

Clinical observations: Transient incidences of dark material around the facial area and fecal staining were observed, but these may be attributed to the use of collar.

Morphological findings: No gross necropsy findings related to the treatment were observed.

Draize scores:

Animal #	***Time after treatment (days)***													
	1	***2***	***3***	***4***	***5***	***6***	***7***	***8***	***9***	***10***	***11***	***12***	***13***	***14***
Erythema														
1	2	2	2	2	2	2	2	1	1	0	0	0	0	0
2	2	2	2	2	1	1	1	1	1	1	1	0	0	0
3	2	2	2	2	2	2	2	2	1	1	0	0	0	0
4	2	3	3	3	2	2	2	2	1	0	0	0	0	0
5	2	2	2	2	2	2	2	2	1	0	0	0	0	0
6	1	2	3	3	3	2	2	2	2	1	1	0	0	0
7	1	1	2	2	2	2	2	2	2	1	1	1	0	0
8	1	1	2	2	2	2	2	2	2	1	1	1	0	0
9	2	2	3	3	3	2	2	2	1	0	0	0	0	0
10	2	2	2	2	2	2	2	2	1	1	1	1		
Oedema														
1	1	1	1	1	1	1	1	1	0	0	0	0	0	0
2	1	1	1	1	1	1	1	1	0	0	0	0	0	0
3	1	1	1	1	1	1	1	1	1	0	0	0	0	0

4	1	2	2	2	2	2	1	1	0	0	0	0	0	0
5	1	1	1	1	1	1	1	1	0	0	0	0	0	0
6	1	1	1	1	1	1	1	1	1	0	0	0	0	0
7	1	1	1	1	1	1	1	1	1	0	0	0	0	0
8	1	1	1	1	1	1	1	1	1	0	0	0	0	0
9	1	1	1	1	2	2	2	1	1	0	0	0	0	0
10	1	1	1	1	2	2	1	1	1	0	0	0	0	0

see Attachment 1 for Draize scales

Comment: The notified chemical was a slight to moderate skin irritant after a 24 hour dermal treatment.

LD_{50}: > 2 000 mg/kg

Result: The notified chemical was of low dermal toxicity in rabbits.

9.1.3 Inhalation Toxicity

No report on acute inhalation toxicity was provided for assessment

9.1.4 Skin Irritation (Merriman, 1995c)

Species/strain: Rabbits/New Zealand White

Number/sex of animals: 6 females

Observation period: 10 days

Method of administration: A single dose of the notified chemical (100%, 0.5 mL) was applied under a semi-occlusive addressing for 4 hours to a small area of intact skin on each animal.

Test method: OECD TG 404

Draize scores:

	Time after treatment					
Animal #	***1 hour***	***1 day***	***2 days***	***3 days***	***7 days***	***10 days***
Erythema						
1	[a]1	1	1	1	1	0
2	1	1	1	2	1	0

3	1	1	1	1	1	0
4	1	1	1	1	0	-
5	1	1	1	1	0	-
6	1	1	1	1	0	-
Oedema						
1	0	0	0	0	0	0
2	1	0	0	1	0	0
3	1	0	0	0	0	0
4	1	1	0	0	0	-
5	0	0	0	0	0	-
6	1	0	0	1	0	-

[a] see Attachment 1 for Draize scales

Comment: Additional observations included desquamation and test site stained brown, which were noted on 5/6 and 6/6 test sites, respectively.

Result: The notified chemical was slightly irritating to the skin of rabbits.

9.1.5 Eye Irritation

No report on eye irritation was provided for assessment.

9.1.6 Skin Sensitisation (Merriman, 1995d)

Species/strain: Guinea pigs/Hartley-derived albino

Number of animals: Test group: 10/sex;
Challenge control group: 5/sex;
Rechallenge control group: 5/sex.

Positive control: 1-chloro-2,4-dinitrobenzene (DNCB)
DNCB test group: 3/sex;
DNCB control group: 2/sex.

Induction procedure:

test group:
day 0

Intradermal Induction:
Three pairs of intradermal injections (0.1 mL) into the scapular area:

- Freund's complete adjuvant (FCA) 1:1 in water;
- 5% notified chemical in propylene glycol;
- 5% notified chemical in a 1:1 mixture of FCA and

water.

day 7 — Topical Induction:
A 48-hour semi-occluded application of 100% notified chemical (0.8 mL) to the test area.

control group: — Treated similarly to the test animals using propylene glycol or DNCB instead of the notified chemical in the intradermal injections and topical application.

Challenge procedure:

day 21 — *Challenge*
Occluded applications of a patch of 40% notified chemical in mineral oil (0.4 mL) for 24 hours.

day 28 — *Rechallenge*
Occluded applications of a patch of 10% and 25% notified chemical in mineral oil (0.4 mL) for 24 hours.

Test method: OECD TG 406

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
40%	**7/20	0/20	3/10	1/10
Rechallenge concentration				
10%	10/20	3/20	1/10	0/10
25%	17/20	10/20	1/10	0/10

* time after patch removal
** number of animals exhibiting positive response

Comment: Most of the test and control animals had slight patchy erythema and very slight oedema, which was likely to be caused by the irritation effect of the notified chemical. Thus, these animals were defined as negative in the challenge and rechallenge.

The positive control DNCB induced appropriate response in the study.

Result: The notified chemical was sensitising to the skin of guinea pigs.

9.2 Repeated Dose Toxicity

9.2.1 28-Day Repeated Dose Toxicity (Iatropoulos et al., 1998)

Species/strain:	Rats/Fischer 344
Number/sex of animals:	8/sex/group: 3 test groups, 1 control group. 6/sex/group: 2 recovery groups (high dose and control)
Method of administration:	Oral (dietary)
Dose/Study duration:	Control group: 0 mg/kg/day; Low dose group: 7.5 mg/kg/day; Mid dose group: 30 mg/kg/day; High dose group: 120 mg/kg/day; Vehicle: olive oil. Animals were fed for 28 consecutive days followed by a 14 day treatment free (recovery) period for the recovery groups.
Test method:	OECD TG 407

Clinical observations
No treatment-related responses were observed. Both male and female animals at high dose had decreases in food consumption and body weight gain from day 1 and day 7, respectively. The food consumption and body weight gain were recovered partially in the recovery group.

Clinical chemistry/Haematology
The males and females at high dose had higher mean corpuscular volume (MCV) at day 29 and concomitantly lower mean corpuscular haemoglobin concentration (MCHC). These changes persisted throughout the recovery period.

At day 29, both high dose male and females had increases in total bilirubin, and cholesterol values, and high dose males also had increases in total protein and albumin. The values of total bilirubin, and cholesterol values were reverted to normal by day 43, but not that of total protein and albumin.

Urinalysis results showed that high dose males and females had higher specific gravity and pH with a concomitant lower volumes. These changes were recovered in females but not in the males throughout the 2-week recovery period.

Pathology
The mid and high dose males had higher liver weights at day 29, which became lower than the controls after the recovery period. The high dose females had lower ovarian and uterine and heart weights at day 29, and these values recovered at day 43.

The males and females at mid and high doses had increases in relative liver weights. The high dose males and females had higher relative kidney and brain weights. In addition, the high dose males had higher relative adrenal weights and the high dose females had lower

ovarian and uterine weights. These changes were recovered on day 43 except the relative kidney and brain weights in males. The pituitary weights, which were normal at day 29, showed increased values in high dose males and decreased values in high dose females at day 43.

In high dose males at day 29, there was some increased incidence of calculi with concretion in the urinary bladder. These changes were in the lumen and did not induce microscopic changes, and were not present at day 43. In addition, an orange discolouration of all fatty tissues, which remained during recovery, was observed in high dose males and females.

Histopathology
Both male (100%) and female (88%) animals at high dose had extramedullary erythropoiesis in the sinusoids of liver at day 29, which was not present at day 43.

Comment
Females at high dose had lower hepatocellular proliferation index at day 29. Urothelial proliferation index (PI) was increased in high dose males and females. The PI in females showed a dose-response pattern, and the PI in males was still high at day 43.

At the high dose in both male and females animals, the notified chemical caused a macrocytic anaemia, leading to bodyweight gain reduction, protein catabolism, changes in plasma blood flow, compensatory extramedullary erythropoiesis, renal overload, reduction in plasma osmotic pressure and disruption of bilirubin metabolism. Additional changes in the renal filtrate and the luminal conditions in the urinary bladder caused adaptive hyperplasia of the urothelium. The anaemia persisted during recovery. Some of these effects such as decrease in food consumption and MCHC, and increase in MCV were not completely reversible within the 14 day recovery period.

Result:
The NOEL was established to be 30 mg/kg/day based on the macrocytic anaemia and other effects at the next (highest) dose of 120 mg/kg/day.

9.2.2 52-Week Repeated Dose Toxicity (Iatropoulos et al., 2000)

Species/strain:	Rats/Fischer 344
Number/sex of animals:	40-week termination: 3 dose groups and 1 control group: 6/sex. 52-week termination: 3 dose groups: 20/sex; 1 control group: 12/sex. 64-week termination: 3 dose groups and 1 control group: 6/sex/group.
Method of administration:	Oral (dietary)
Dose/Study duration:	Control group: 0 mg/kg/day;

Low dose group: 60 ppm (4 mg/kg/day);
Mid dose group: 300 ppm (20 mg/kg/day);
High dose group: 1 500 ppm (100 mg/kg/day)
(Vehicle: olive oil).

Animals were fed for 40 and 52 consecutive weeks for the 40 and 52-week termination groups, respectively. The 64-week termination groups were fed for 52 weeks followed by a 12-week treatment free (recovery) period.

Test method: OECD TG 452

Clinical observations:
Three males and one female in the 64-week termination group were found dead or sacrificed moribund. These unscheduled deaths were not attributable to dosing.

Dose level	Male/ Female	Death time (week)	Findings
High	F	25	Granulomatous inflammation in mesenteric lymph node. Pulmonary congestion with oedema and a papilloma in forestomach.
High	M	29	Diffuse pulmonary haemorrhage and myocardial fibrosis.
High	M	59	Granulomatous inflammation in mesenteric lymph node.
Mid	M	57	Granulomatous inflammation in mesenteric lymph node. Multiple ulcerative lesions in forestomach and a chromophobe adenoma in pituitary.

No treatment-related clinical signs were observed. Food and water consumption was comparable with controls. High dose male and female animals demonstrated decreased bodyweight gain throughout the study. The body weight gain was similar to control animals during the recovery phase.

Clinical chemistry/Haematology:
High dose males and females had a higher mean corpuscular volume (MCV) by week 40. This change was seen only in females by week 52. Concomitantly a lower mean corpuscular haemoglobin concentration (MCHC) was observed in high–dose females at weeks 40 and 52. Red blood cell counts (RBC) and haemoglobin (HGB) values were decreased in high-dose males at weeks 40 and 52. All parameters showed improvement by week 64.

Increases in methemoglobin were observed in mid and high-dose males at week 40, in high-dose females at week 52, and in mid-dose females and high-dose animals at week 64. Prothrombin time was shortened in mid-dose males and high-dose animals at week 52. After the recovery period, these parameters improved in males but worsened in both mid and high-dose females. In addition, increase in platelet count and decreases in RBC, HGB, hematocrit (HCT) and activated partial thromboplastin time (APTT) in males were seen by

weeks 40 and 52, and the reticulocyte count was increased in mid-dose males and high-dose animals by week 52. High dose males and females had lower serum folate levels at weeks 40 and 52, and lower folic acid at week 52, with partially recovery after the recovery period. High-dose females had lower serum iron levels at weeks 40 and 52.

The above changes in clinical chemistry and haematology indicated a presence of chronic methemoglobinemia and a chronic macrocytic anaemia, possibly due to chronic folate and iron deficiencies. Increased reticulocyte counts at week 52 indicated erythroid regeneration.

Results in male animals showed increases in AST (mid-dose at week 40), cholesterol (high-dose at week 52), and total serum bilirubin (high-dose at weeks 40 and 52). Results in female animals showed increases in leucine aminopeptidase (LAP) (high-dose at week 52), unsaturated iron binding capacity (UIBC) (high-dose at week 40 and 52), transferrin (all doses at week 40) and erythropoietin (high-dose at week 64), and decreases in albumin/globulin ratio (high-dose at week 52) and total iron binding capacity (TIBC) (high-dose at week 52).

Urinalysis results showed lower pH in low and high-dose females at week 52, and lower urine volumes in mid-dose females at week 52.

Pathology:
A significant reduction in terminal bodyweight was observed in high-dose males and an increase in relative liver, kidney and thyroid weight was seen in the high-dose animals of both sexes, at week 52.

Orange discolouration of body fat was present in the treated animals sacrificed at weeks 40 (mid and high-dose, 100%), 52 (all doses, 100%) and 64 (high-dose males and mid/high-dose females, 100%). This finding was attributed to the presence of the test material.

Extensive congestion of the spleen was observed in mid and high-dose males and females, and the high-dose females also demonstrated a low incidence of transitional cell (urothelial) hyperplasia in the urinary bladder.

Increased replicating fraction (RF) values of urinary bladder were observed in high-dose males and females at week 40, with partial recovery by week 64.

None of the neoplasms observed in the study were considered to be treatment related.

Comment

The following changes were assessed as treatment related:

- A reversible reduction in bodyweight gain in high-dose animals at week 52.
- Haematological and chemical changes in MCV, MCHC, RBC, HGB, serum iron and folate in mid and high-dose animals indicated a presence of macrocytic anaemia probably due to iron and folate deficiencies.
- Compensatory changes in spleen, liver, kidney and bladder in high-dose animals provided further evidences for macrocytic anaemia.

In this study, the dietary treatment at high-dose produced a very mild methemoglobinemia, macrocytic anaemia, interference with folate, iron, erythropoietic and circulatory homeostases resulting in chronic stimulation of the urothelium in the urinary bladder with increased proliferation.

The neoplasms observed in the study were not considered to be treatment related.

Result:
The NOEL was established at 60 ppm (4 mg/kg/day) based on the macrocytic anaemia and other effects at the next highest dose.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay (Stankowski, 1998)

Strains:	*Salmonella typhimurium* TA1535, TA1537, TA1538, TA98 and TA100; *Escherichia coli* WP2*uvr*A.
Metabolic activation:	Liver fraction (S9 mix) from rats pretreated with Aroclor 1254.
Concentration range:	Mutation assay: For *Salmonella* strains, 0, 0.167, 0.5, 1.67, 5.0, 16.7 and 50.0 µg/plate in the presence and absence of S9-mix. For *E. coli*. strain, 0, 1.67, 5.0, 16.7, 50.0, 167, 500 µg/plate in the presence and absence of S9-mix (vehicle: DMSO). Confirmatory assay: For *Salmonella* strains, 0, 1.67, 5.0, 16.7, 50.0, 167, 500 µg/plate in the presence of S9-mix, and 0, 0.167, 0.5, 1.67, 5.0, 16.7, 50.0 µg/plate in the absence of S9-mix (vehicle: DMSO). For *E. coli*. strain, 0, 1.67, 5.0, 16.7, 50.0, 167, 500 µg/plate in the presence and absence of S9-mix (vehicle: DMSO). Positive controls:

(without S9-mix)
sodium azide for TA1535 and TA100;
9-aminoacridine for TA1537;
2-notrofluorene for TA1538 and TA98;
ENNG for WP2*uvr*A.

(with S9-mix)
2-anthramine for all strains.

Test method: OECD TG 471

Comment: The notified chemical was not toxic to *E. coli* strain up to 5 mg/plate, but inhibited growth was observed in *Salmonella* strains 5.0, 16.7 and/or 50 μg/plate without S9. Precipitation was observed at doses ≥16.7 and ≥50 μg/plate in the mutation and confirmatory assays, respectively.

In both mutation and confirmatory assays, revertant frequencies for all doses in TA1535, TA100 and WP2*uvr*A with S9, and in all tested strains without S9 were less than those observed in the concurrent negative control cultures. Statistically significant dose-dependent increases in revertant frequencies to approximately 2.3 to 33 fold control values were observed in TA1537, TA1538 and TA98 with S9.

All positive and negative control values were within acceptable ranges.

Result: The notified chemical was mutagenic under the conditions of the test.

9.3.2 Chromosomal Aberration Assay in Chinese Hamster Ovary (CHO) Cells (SanSebastian, 1994a)

Cells: Chinese Hamster Ovary (CHO) Cells

Metabolic activation system: Liver fraction (S9 mix) from rats pretreated with Aroclor 1254.

Dosing schedule:

Metabolic Activation	Experiment/ Study Number	Test concentration (μg/mL)	Controls
-S9	I II III	treatment time = 5 hours 0, 0.5, 2.5, and 5 treatment time = 24 hours 0, 0.5, 5, and 25 treatment time = 48 hours 0, 0.5, 2.5 and 5	Positive: MNNG Negative: DMSO
+S9	I	treatment time = 5 hours 0, 5, 25 and 50	Positive: DMN Negative: DMSO

DMN - N-nitrosodimethylamine
MNNG: N-methyl-N'-nitro-N-nitrosoguanidine
DMSO – dimethylsulphoxide

Test method: OECD TG

Comment: In a cytotoxicity test, the notified chemical induced cell death at doses ≥25 μg/mL without S9 and ≥250 μg/mL with S9. Osmolality and pH were not changed when cells were treated with the notified chemical.

There was no statistically significant increase in the frequency of aberrations/metaphase or in the proportion of aberrant metaphases at any the doses and time period of treatment in the study.

All positive and negative control values were within acceptable ranges.

Result: The notified chemical was non clastogenic under the conditions of the test

9.3.3 Micronucleus Assay in the Bone Marrow Cells of the Mouse (SanSebastian, 1994b) (Wingstay 100)

Species/strain: Mouse/CD-1

Number and sex of animals: 5/sex/group

Doses: 0, 250, 1 250 and 2 500 mg/kg
(vehicle: DMSO and corn oil).

Negative control: vehicle.
Positive control: triethylenemelamine (TEM).

Test animals were sacrificed 24, 48 and 72-hours post-treatment. The positive control animals were sacrificed 24-hours post-treatment.

Method of administration: A single intraperitoneal dose.

Test method: OECD TG 474

Comment: Two males at 1 250 mg/kg and two males and one female at 2 500 mg/kg died during the study. Abnormal gait, abnormal stance, flaccid body tone, piloerection and writhing were seen in animals at 250 mg/kg and became worse at higher doses. Additionally, decreased activity, ptosis and salivation were observed in animals at 1 250 and 2 500 mg/kg.

There were no statistically significant increases in the frequency of micronucleated polychromatic erythrocytes (MPCEs) in test animals when compared to negative controls. There were no statistically significant depressions in the PCE/normochromatic erythrocytes (NCE) ratios in any group of mice except for the group at 2 500 mg/kg sacrificed at 48 hours. This suggests that Wingstay 100 reached bone marrow and was toxic to the erythrocytes.

The positive control group had appropriate responses.

Result: Wingstay 100 was non-clastogenic under the conditions of the test.

9.3.4 Unscheduled DNA Synthesis Assays (UDS) in Rat Hepatocytes (Jeffrey, 1999)

Cells: Hepatocytes from male Fischer 344 rat.

Test material: Wingstay 200;
R-59: diphenyl-*p*-phenylenediamine (DPPD) (CAS 74-31-7);
R-898: dimethyl DPPD (CAS 15017-02-4);
R-6304: 2,2',4,4'-tetramethyl DPPD.
(R-59, R-898 and R-6304 are the components of Wingstay 200).

Dosing schedule: treatment time = 18-20 hours.

Assay	Test concentration (µg/mL)		Controls
First assay	Wingstay 200:	20*, 4*, 0.8 and 0.16;	Positive: 2-aminofluorene
	R-59:	2 and 0.4;	
	R-898:	5*, 1*, 0.2 and 0.04;	Negative: Fluorene
	R-6304:	10*, 2*, 0.4 and 0.08.	

Second assay	Wingstay 200:	16*, 8*, 5*, 2.5, 1.25 and 0.625;	Solvent: 1% DMSO in Williams Medium E.
	R-59:	8*, 4*, 2, 1 and 0.5;	
	R-898:	16*, 8*, 5*, 1*, 0.5 and 0.25;	
	R-6304:	16*, 8*, 5*, 2.5*, 1.25 and 0.625.	

* cytotoxic response occurred.

Test method: OECD TG 482

Comment: Viabilities of harvested hepatocytes for the 2 assays were >99%.

Precipitation occurred at 6, 5, 10 and 20 µg/mL for Wingstay 200, R-59, R0898 and R-6304, respectively. All 4 test materials were tested at the concentrations slightly above their limits of solubility in the tissue culture medium or until they became too toxic to test.

Wingstay 200 and R-6304 showed weakly positive values for net nuclear grains and positive values, respectively at cytotoxic concentrations. R-59 and R-89 showed negative net nuclear grains at cytotoxic concentrations.

The positive and negative controls had appropriate responses.

Result: Wingstay 200, R-59, R-898 and R-6304 were negative in the conventional UDS assay at non-cytotoxic concentrations.

9.4 Developmental Toxicity in Rats (Tyl, 1996)

Species/strain: Rat/Sprague-Dawley CD.

Number/sex of animals: 25 mated females per dose group.

Method of administration: Oral by gavage.

Dose/Study duration: Control group: 0 mg/kg/day;
Low-dose group: 20 mg/kg/day;
Mid-dose group: 70 mg/kg/day;
High-dose group 1: 200 mg/kg/day;
High-dose group 2: 200 mg/kg/day (vehicle: corn oil).

After mating, animals were treated once daily during days 6-19 of gestation except a treatment duration of days 6-15 for high-dose group 2. All animals were sacrificed on day 20.

Test method: OECD TG 414

Maternal observations:
One female at mid-dose was found dead on day 19 of the study. One low-dose female was removed from the study due to a suspected pre-existing condition, and another high-dose female was removed due to a dosing error. All other animals survived to scheduled sacrifice.

Maternal bodyweights and food consumptions in the mid and high-dose females were reduced. The food consumptions in the animals of high-dose group 2 were increased after the treatment ceased on day 15.

Piloerection was seen in all the groups, but the frequencies became higher in a dose-related pattern. Rooting (a loud noise) post-dosing was observed in 2 animals at high-dose

Foetal observations:
The mid-dose group and 2 high-dose groups had lower foetal bodyweight per litter when calculated as all foetuses or males or females separately.

Other litter data were comparable across all groups including the control group.

Necropsy:
F_0 generation: Gravid uterine weights in test groups were reduced in a dose-related pattern. The mean liver weights were comparable in all groups including the control group. However, increases in the ratio of liver weight to bodyweight were seen in the mid-dose group and 2 high-dose groups. One dam at mid-dose had bilateral hydronephrosis.

F_1 generation: One mid-dose foetus exhibited various external malformations including anasarca (whole body oedema), microdactyly (small digits) fore and hind paw, ectrodactyly (missing digits) in forepaw and micromelia (short limbs). Visceral and skeletal malformations, and visceral and skeletal variations were observed in all groups including the control group at similar incident rates.

Incidence of Malformation and Variation in Foetuses and Litters
(incidence/number examined)

			Control	***Low-dose***	***Mid-dose***	***High-dose 1***	***High-dose 2***
Malformatio	External	Foetus	0/339	0/327	1/296	0/323	0/334
		Litter	0/25	0/23	1/22	0/23	0/24
	Visceral	Foetus	2/339	4/327	1/296	3/323	0/334
		Litter	2/25	1/23	1/22	2/23	0/24
	Skeletal	Foetus	1/168	0/165	0/146	1/163	0/166
		Litter	1/25	0/23	0/22	0/23	0/24
Variation	External	Foetus	0/339	0/327	0/296	0/323	0/334
		Litter	0/25	0/23	0/22	0/23	0/24
	Visceral	Foetus	51/339	38/327	34/296	52/323	48/334
		Litter	18/25	16/23	16/22	20/23	17/24
	Skeletal	Foetus	13/168	14/165	7/146	18/163	21/166
		Litter	8/25	8/23	4/22	10/23	14/24

Comment:

Historical data from developmental studies were provided in the report. The following changes were considered to be treatment related:

In F_0 animals, decreases in bodyweights, bodyweight gains, and food consumption at mid and high-dose levels; there was no evidence for maternal toxicity at low-dose level.

In F_1 animals, developmental toxicity was observed as reduced foetal bodyweights at mid and high-dose levels. There was no evidence for teratogenic toxicity at all dose levels. All foetal malformation and variation findings were within historical control data ranges in the test laboratory and in published control databases.

Result:
The NOEL is determined to be 20 mg/kg/day for maternal and developmental toxicity in rats under the conditions of this study.

9.5 Overall Assessment of Toxicological Data

Wingstay 200 was of very low acute oral toxicity in rats and low acute dermal toxicity in rabbits. In rabbits, it was a slight skin irritant when exposed to the notified chemical for 4 hours and became a slight to moderate skin irritant when exposed for 24 hours. The notified chemical was a skin sensitiser in guinea pigs. No reports on acute inhalation or eye irritation were provided.

Two repeat dose dietary studies in rats were provided. The NOEL from the 52 week study was 60 ppm (4 mg/kg/day) based on macrocytic anaemia and other effects at the next dose. The NOEL for maternal and developmental toxicity in rats was 20 mg/kg/day based on the decreases in bodyweights, bodyweight gains and food consumption in F_0 animals, and a decrease in foetal bodyweights in F_1 animals at 70 mg/kg/day and higher.

The notified chemical was mutagenic in a reverse mutation assay in bacteria. It was non-clastogenic in the *in vitro* chromosomal aberration assay in CHO cells. Wingstay 200 and its components R-59, R-898 and R-6304 were found negative in the conventional UDS assay at non-cytotoxic concentrations in rat hepatocytes. The notifier provided an *in vivo* micronucleus assay in the bone marrow cells of mouse for Wingstay 100. Wingstay 100 has similar chemical structures to Wingstay 200 except a lower degree of methyl substitution on the aryl rings. Wingstay 100 was non-clastogenic based on its inability to induce micronucleated PCEs.

According to NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b), the notified chemical is classified as a hazardous substance based on skin sensitisation and long term haematological effects. The proposed risk phrases for Winstay 200 is R43 (May cause sensitisation by skin contact) and R48/22 (Harmful: danger or serious damage to health by prolonged exposure if swallowed).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies conducted on Wingstay 200 were assessed. The tests were carried out according to OECD Test Methods.

Test	*Species*	*Results*	*Reference*
Prolonged Acute Toxicity (OECD TG 204)	Common Carp *(Cyprinus carpio)*	14 d LC_{50} = 0.35 mg/L 14 d LOEC = 0.35 mg/L 14 d NOEC = 0.17 mg/L	Dionne, 1998
Acute Toxicity (OECD TG 115)	Water Flea (*Daphnia magna*)	48 h EC_{50} = 0.59 mg/L NOEC = 0.18 mg/L	Putt, 1998
Acute Toxicity (OECD TG 201)	Algae (*Selenastrum capricornutum*)	72 h E_bC_{50} = 9.4 µg/L 72 h E_rC_{50} = 0.11 mg/L NOEC = 0.0020 mg/L	Hoberg, 1998

Fish

The prolonged acute test on carp was performed under flow-through conditions over 14 days (Dionne, 1998). Two replicate tanks containing ten fish in each were set up for each test concentration (nominally 0.062, 0.14, 0.30, 0.68 and 1.5 mg/L), solvent control and test controls and illuminated for 16 h/day. During the tests the temperature was between 21-22ºC, the pH was between 6.7 and 7.3 and conductivity 140 to 150 µmhos/cm.

The test solutions were prepared by firstly making a stock solution of 20 mg/mL in acetone. A 1.5 mg/L secondary stock solution was prepared daily, mixed for 1 hour and allowed to settle for 1 hour. The water accommodated fraction of the stock was diluted with sterile medium to the appropriate concentrations and pumped continuously through the test tanks at 50 mL/min. Analysis by HPLC of nominal test solutions gave the following mean measured concentrations: 0.032, 0.075, 0.17, 0.35 and 0.89 mg/L.

After 7 days exposure, 100% mortality occurred in fish exposed to the highest concentration (0.89 mg/L). At the end of test (day 14), mortality of 5% and 59% was observed among fish exposed to 0.17 and 0.35 mg/L, respectively. Sublethal effects (eg lethargy, loss of equilibrium) were observed among fish exposed to the remaining treatment levels, 0.032 and 0.075 mg/L. Mortality of 5 and 0% was observed in the control and solvent control, respectively, so the mortality of 5% observed in the 0.17 mg/L treatment tank was not considered an adverse response. The 14 day LC_{50} for the notified chemical was calculated by moving average angle analysis to be 0.35 mg/L with corresponding 95% confidence interval of 0.29 to 0.42 mg/L.

Daphnia (Acute Immobilisation)

The tests on *Daphnia magna* were conducted over a 48 hour period, using a flow-through test methodology (see above) (Putt, 1998). Two replicate tanks containing ten daphnids in each were set up for each test concentration (nominally 0.19, 0.32, 0.54, 0.90 and 1.5 mg/L), solvent control and test controls and illuminated for 16 h/day. During the tests the temperature was 20ºC, the pH was between 8.0 and 8.2, dissolved oxygen 8.7 to 9.3 mg/L and conductivity 500 µmhos/cm.

The stock solution was prepared in acetone. The test solutions were prepared by firstly making a stock solution of 15 mg/mL. A 1.5 mg/L secondary stock solution was prepared daily, mixed for 1 hour and allowed to settle for 1 hour. The water accommodated fraction of the stock was diluted with sterile medium to the appropriate concentrations and pumped

continuously through the test tanks at 50 mL/min. Analysis by HPLC of these nominal test solutions gave the following mean measured concentrations: 0.087, 0.18, 0.27, 0.46 and 0.81 mg/L.

At the test end, there was 100% immobilisation of the daphnids in the 0.81 mg/L tanks, 5% immobilisation at 0.46 mg/L and no immobilisation at the lowest three treatment levels. Adverse effects (lethargy) were observed among all the daphnids exposed to 0.46 mg/L and several of those exposed to 0.27 mg/L. The 48 h EC_{50} value for the notified chemical was estimated by nonlinear interpolation to be 0.59 mg/L.

Algae

A limit test on the inhibition of algal growth was also conducted on *Selanastrum subspicatus* over a 72 hour incubation period at 24-25ºC with nominal concentration of the test material of 0.0024, 0.0081, 0.027, 0.090, 0.30 and 1.0 mg/L (Hoberg, 1998). The stock solution was prepared in acetone. The test solutions were prepared by firstly making a stock solution of 10 mg/mL. Appropriate volumes of this primary stock solution were then diluted to 10 mL with acetone to create secondary stock solutions then further diluted with sterile medium to prepare the test solutions. Analysis by HPLC of these nominal test solutions gave the following mean measured concentrations: 0.0020, 0.0042, 0.016, 0.047, 0.16 and 0.33 mg/L.

Three replicate tests for each concentration (except 0.090 mg/L with four replicates) were conducted in 250 mL Erlenmeyer flasks, together with three solvent and three non-solvent control flasks containing no chemical. Each flask contained 100 mL of the test medium and was inoculated with $1.0x10^4$ cells/mL of the algae. The flasks were continuously shaken on an orbital shaker. The temperature of the test solutions remained between 24-25ºC and pH ranged from 7.2 at the start to 8.7 at the test termination. The growth of algal biomass was determined over the test period by removing aliquots which were centrifuged and counted by light microscopy. The average specific growth rate was measured for each replicate flask during the experimental period using daily cell counts. Growth curves were calculated for each test concentration and the area under each curve determined. The results are given in the table above.

The ecotoxicity data indicate that the chemical is highly toxic to fish and aquatic invertebrates and very highly toxic to algae (Mensink et al, 1995).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The maximum expected concentration of chemical released by the squeezing of rubber crumbs into the primary discharge water is 1.02 mg/L. The primary discharge water is diluted 1:2 in the final Qenos plant effluent and discharged into the Werribee Treatment Plant. The notifier estimates that the Qenos discharge is around 500 kg/min (or 720 000 L/day), resulting in a discharge of the new chemical of approximately 360 g/day into the Werribee Treatment Plant, which has a flow of 500 ML/day. Therefore the concentration of the chemical into and out of the Werribee Plant would be around 0.72 µg/L, assuming no removal during treatment. On discharge to receiving waters further dilution of at least 1:10 is expected giving a PEC of 0.072 µg/L.

The notified chemical is highly to very highly toxic to aquatic species, with the E_bC_{50}(72 h) for algae (the most sensitive species) being 9.4 µg/L. However, the calculated PEC in

receiving waters of 0.072 µg/L indicates a safety margin of 2 orders of magnitude once the treated sewage is discharged to sea. It should also be noted that releases of the chemical to the sewer will take place on only 6 days/annum.

The chemical is expected to have a significant potential for bioconcentration based on the low molecular weight, intermediate value for Log Pow (3.5-4.6) and water solubility (1 mg/L), but is not expected to enter the aquatic environment in sufficient quantities to bioaccumulate.

If the used rubber articles are combusted, the notified chemical will be destroyed.

The small proportion of the chemical that may enter the soil environment through wear and tear of tyres or shredding of used rubber articles for the manufacture of other items will be in a highly dispersed manner and is expected to be slowly degraded through biological processes.

The environmental hazard from the notified chemical is rated as low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Wingstay 200 was of very low acute oral toxicity and low acute dermal toxicity. It was a slight skin irritant and a skin sensitiser. No reports on acute inhalation or eye irritation were provided. Repeat dose dietary studies in rats showed a NOEL of 4 mg/kg/day based on development of macrocytic anaemia. The notified chemical was mutagenic in the Ames Test but non clastogenic in CHO cells chromosomal aberration assay. Wingstay 200 and its components R-59, R-898 and R-6304 were negative in the conventional UDS assay at non-cytotoxic concentrations. Wingstay 200 is also expected to be non-clastogenic in *in vivo* micronucleus assay based on analogue data. According to NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b), the notified chemical is classified as a hazardous substance with risk phrases of R43 (May cause sensitisation by skin contact) and R48/22 (Harmful: danger or serious damage to health by prolonged exposure if swallowed).

Precautions should be taken as the notified chemical is a skin sensitiser. Any individuals who become sensitised should not continue to handle the notified chemical.

Occupational health and safety
Exposure to the notified chemical is not expected during transport or storage as long as the packaging of sealed steel drums remains intact. The risk of adverse health effects for transport and storage workers is considered to be low.

The notified chemical will be initially manufactured with other ingredients into rubber blocks such as SBR 1500, which will then be further blended at other sites to produce the final rubber products. During the processes of processing rubber blocks, dermal exposure may be experienced by workers when opening drums, connecting and disconnecting suction pumps during transfer operations. The mixing and extrusion processes are described as enclosed and automated, therefore exposure would be limited. The production facilities are fitted with vacuum extraction equipment to trap fugitive dust and vapour emissions and bunding to contain liquid spills and leaks. All workers involved in the production of rubber blocks will wear protective equipment including gloves, safety glasses and overalls. Based on the use of

engineering controls and personal protective equipment, the health risk to workers during the rubber block manufacturing is expected to be low. After processing, the notified chemical is encapsulated within the rubber matrix at approximately 1%, and not available for absorption.

Little dermal exposure to the notified chemical is expected for workers handling the pre-compounded rubber blocks or SBR 1500 at the rubber products manufacturing sites. As the notified chemical is encapsulated in the polymer matrix and will not be available for exposure, therefore the risk of adverse health effects from rubber product manufacture is assessed as low.

The notifier stated that there has been a long history of use this class of chemical as antioxidants in synthetic rubber production. To date, no work-related injuries or adverse health effects associated with the notified chemical have been reported. In addition, a workplace risk assessment will be carried out under State Hazardous Substances Regulations.

Public health
The imported notified chemical will not be sold to the public. The public will come into contact with the rubber products (car and truck tyres) containing the notified chemical. Given the low concentration of notified chemical in the products and their use pattern, notified chemical incorporated into the rubber matrix is expected to be biologically unavailable, and will not pose a significant risk to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to Wingstay 200, the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); industrial clothing should conform to the specifications detailed in AS 2919 and AS 3765.2 (Standards Australia, 1990); impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia/Standards New Zealand, 1998); all occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994a);

- Caution should be exercised as the notified chemical is a skin sensitiser. Individuals who become sensitised should not continue to handle the notified chemical;

- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;

- A copy of the MSDS should be easily accessible to employees.

If products containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b), workplace practices and control procedures consistent with State and territory hazardous substances regulations must be in operation.

The notified chemical may be recommended to the National Occupational Health and Safety Commission (NOHSC) for consideration for inclusion in the NOHSC List of Designated Hazardous Substances with R43 (May cause sensitisation by skin contact) and R48/22 (Harmful: danger or serious damage to health by prolonged exposure if swallowed).

To minimise environmental exposure to Wingstay 200, incineration is the recommended method for disposal of drum residues.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under subsection 64(2) the Act, secondary notification of the notified chemical may be required if any of the circumstances stipulated arise. No other specific conditions are prescribed.

16. REFERENCES

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Attachment 1

The Draize Scale (Draize, 1959) for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale (Draize *et al*., 1944) for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe

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