File No: NA/971

November 2001

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

SX9509

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

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

SX9509

1. APPLICANT

Océ-Australia Limited (ACN 004 315 913) of 2 International Court, Scoresby, VIC 3178 has submitted a standard notification statement in support of their application for an assessment certificate for SX9509. .

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, exact use and import volume have been exempted from publication in the Full Public Report and the Summary Report.

Marketing Name:	SX9509
Spectral Data:	UV/Vis, IR and EDX spectra were provided.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa:	Grey powder
Boiling Point:	Melting of notified chemical was not observed but reaction/decomposition occurs above 67°C.
Specific Gravity:	6540 kg/m3 at 20°C
Vapour Pressure:	6.6 x 10-5 kPa at 20°C
Water Solubility:	< 10 microgram/L
Partition Co-efficient (n-octanol/water):	Not applicable to inorganic substances. SX9509 has low solubility in both water and octanol.
Hydrolysis as a Function of pH:	Not applicable to this poorly soluble inorganic substance.
Adsorption/Desorption:	Test not performed because of low solubility.
Dissociation Constant:	Not applicable to this inorganic substance.

Flash Point:	Not applicable for solids.
Flammability Limits:	Chemical could not be ignited with a flame, no flames or sparks were observed.
Autoignition Temperature:	Not self-ignitable.
Explosive Properties:	Not explosive.
Reactivity/Stability:	Has no oxidising properties; not known to be incompatible with certain chemicals; stable; hazardous decomposition product: hydrogen fluoride.
Particle Size:	Mass median diameter: 1.30 micron; 96% < 10.5 micron; particle size of toner products is 9 – 15 micron.
Fat Solubility	< 2 mg/100g (at 37°C)
Surface Tension:	72.3 nN/m (at 20°C); not surface active.

3.1 Comments on Physico-Chemical Properties

Specific gravity was determined using the gas comparison pycnometer method, vapour pressure by static technique and water solubility using the column elution method.

4. PURITY OF THE CHEMICAL

Degree of Purity:	> 98%
Hazardous Impurities:	2 hazardous impurities at < 0.1% (both strong acids).
Non-hazardous Impurities (> 1% by weight):	One impurity up to 2%.
Additives/Adjuvants:	None.

5. USE, VOLUME AND FORMULATION

The notified chemical will be used as a component of a colour toner in professional (key operator) copying and printing equipment in the reprographic industry to be used in printing/copying centres. No reformulation of repackaging of toner will occur in Australia. Less than 10 tonnes of the notified chemical will be imported per year for the first five years.

6. OCCUPATIONAL EXPOSURE

Waterside, warehouse and transport workers are unlikely to be exposed to the notified chemical unless the packaging is breached.

Machine operators and machine maintenance workers may be intermittently exposed to the notified chemical contained in the toner bottle when replacing the spent container, and during repair maintenance and cleaning of printers or photocopiers. Maintenance workers for printers or photocopiers may potentially come in contact with the notified chemical more often than office workers. Exposure is expected to be controlled through the design of the bottles and the printing or photocopying machines. Printer or photocopier maintenance personnel often wear cotton disposable gloves. Pre-packed bottles are sealed and worker exposure to the toner is minimised by the use of the replacement procedures recommended by the manufacturer. The number of sites and number of workers potentially exposed to the notified chemical are unknown but a maximum of approximately 1000 bottles of toner will be imported per year for the first 5 years.

Contact with paper printed with toner containing the notified chemical is unlikely to result in dermal exposure, as it will be bound in the structure of the paper.

7. PUBLIC EXPOSURE

It is possible that following transport accidents involving breakage of the polyethylene containers in windy conditions, members of the public may be subjected to dermal, eye, nasal or mouth contact with windborne toner powder containing the notified chemical at a low concentration. The likelihood of the occurrence of such a combination of events is very low. The escape of toner dust from copying and printing plants is negligible. The toner powder containing the notified chemical is not expected to be available for use by the public. Any dermal contact the public may have with the notified chemical on printed paper or other material, is unlikely to result in the transference of the notified chemical to the skin. The potential for the exposure of the public to the notified chemical is therefore negligible.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

The notifier states that more than 98% of the imported toner will be fixed to paper (and other specialty image carriers such as polyester sheet) with most of the remainder to be returned to the notifier as toner waste. Release to the atmosphere is estimated by the notifier to be approximately 0.001%.

Releases from transfer operations are expected to be minimal as the product is imported in ready-for-use containers which are emptied directly into copying and printing equipment. As the product is a powder, any accidental spills can be readily managed by vacuum collection and disposal to landfill. No releases to water are expected from normal use of the product.

8.2 Fate

Releases to the environment are not expected to be bioavailable because of low solubility and the resistance of the metal oxide bond to biological attack. Toner wastes are usually disposed of to landfill, and may also be generated when paper is recycled. Release to the environment of water soluble compounds, for example by leaching from landfill or passage through sewage treatment works, is expected to be negligible because of retention by soil or sludge.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of SX9509

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD50 > 2000 mg/kg	(Notox, 1996a)
acute inhalation toxicity	rat	LC50 > 6.92 g/m3	(TNO, 1996)
skin irritation	rabbit	Non-irritating	(Notox, 1996b)
eye irritation	rabbit	Slight irritation	(Notox, 1996c)
skin sensitisation	guinea pig	Non-sensitising	(Notox, 1996d)

9.1.1 Oral Toxicity (Notox, 1996a)

Species/strain:	Rat/Wistar
Number/sex of animals:	5/sex
Observation period:	15 days
Method of administration:	Oral gavage at 2000 mg/kg; vehicle: distilled water.
Test method:	OECD TG 401
Mortality:	No mortality.
Clinical observations:	No clinical signs.
Morphological findings:	No abnormalities were found at macroscopic post mortem examination of the animals.
LD_{50}*:*	> 2000 mg/kg body weight
Result:	The notified chemical was of very low acute oral toxicity in rats

9.1.2 Dermal Toxicity

No data provided.

9.1.3 Inhalation Toxicity (TNO, 1996)

Species/strain:	Rats/Wistar
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	The group was exposed by inhalation to the limit concentration of at least 6.92 ± 0.35 g/m^3 for a 4-hour period. Particle MMAD 1.5 micron. The rats were exposed to the test atmosphere in a nose-only inhalation chamber.
Test method:	OECD TG 403
Mortality:	No mortality occurred.
Clinical observations:	During exposure a slightly decreased breathing rate developed in animals in the last 3 hours of exposure as well as slight laboured breathing in 4 animals in the last hour of exposure. Nine out of ten rats were sluggish and demonstrated slight blepharospasm. All animals showed piloerection. Sluggishness and piloerection were no longer seen on day 1, whereas blepharospasm lasted one day longer in 4/10 rats.
Morphological findings:	Treatment related changes at necropsy consisted of discoloration of the lungs in all animals. In addition, spotted lungs were found in two female rats.
LC_{50}:	> 6.92 g/m^3
Result:	The notified chemical was of low acute inhalation toxicity in rats.

9.1.4 Skin Irritation (Notox, 1996b)

Species/strain:	Albino rabbit/New Zealand White.
Number/sex of animals:	3 males
Observation period:	72 hours
Method of administration:	0.5 grams of the test substance was moistened and applied to the intact skin of the shaved area on one flank, using a semi-occlusive dressing for a period of 4 hours.
Test method:	OECD TG 404

Comment: Neither erythema nor oedema was observed in any animal at any time point. No signs of systemic intoxication were observed during the study period.

Result: The notified chemical was non-irritating when applied to intact rabbit skin.

9.1.5 Eye Irritation (Notox, 1996c)

Species/strain: Albino rabbit/New Zealand White

Number/sex of animals: 3/males

Observation period: 7 days

Method of administration: Single sample of 45 mg (0.1 mL) of SX9509 was instilled in the conjunctival sac of one eye of each rabbit. Fluorescein (2% in water) was instilled into both eyes after 24 hours to determine corneal epithelial damage. Observations were made 1, 24, 48 and 72 hours and 7 days after instillation.

Test method: OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation														
Animal	***1 hour***			***1 days***			***2 days***			***3 days***			***7 days***		
Cornea	Draize scores for cornea (opacity and area) were zero for all animals during the study.														
Iris															
1	1[1]			0			0			0			0		
2	1			0			0			0			0		
3	1			0			0			0			0		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	2	3	1	2	1	0	1	0	0	1	0	0	0	0	0
2	2	2	1	2	0	0	1	0	0	1	0	0	0	0	0
3	2	2	1	2	0	0	1	0	0	1	0	0	0	0	0

[1] see Attachment 1 for Draize scales
o = opacity a = area r = redness c = chemosis d = discharge

Comment: Mean scores for each animal (24, 48 and 72 hours):
Cornea: 0:0:0
Iris: 0:0:0
Conjunctival

Redness: 1.33:1.33:1.33
Conjunctival
Chemosis: 0.33:0:0

Result: The notified chemical was a slight to moderate irritant to the eyes of rabbits.

9.1.6 Skin Sensitisation (Notox, 1996d)

Species/strain: Albino guinea pig (female)/Dunkin Hartley

Number of animals: 10 test and 5 control

Induction procedure:

test group:

day 1 Three pairs of intradermal injections (0.1mL/site) were made in the shoulder region:

- Freund's Complete Adjuvant (FCA), diluted 50:50 with water
- The notified chemical at a 5% concentration
- 10% notified chemical, emulsified in a 50:50 mixture of FCA

day 7 The shoulder area was rubbed with 10% sodium-dodecyl-sulfate (SDS) in vaseline to provoke a mild inflammatory reaction.

day 8 0.5 mL of a 50% concentration of the notified chemical was topically applied to the clipped shoulder area using a semi-occlusive patch for 48 hours.

control group: Control animals were treated similarly to the test animals except without the notified chemical.

Challenge procedure:

day 22 50 %, 25% and 10% notified chemical (0.05mL) was applied topically to flanks for 24 hours under Square chambers attached to Micropore tape.

Test method: OECD TG 406

Challenge outcome:

Challenge concentration	• *Test animals*		• *Control animals*	
	• *24 hours**	• *48 hours**	• *24 hours*	• *48 hours*

10%	**0/9	0/9	0/5	0/5
25%	0/9	0/9	0/5	0/5
50%	0/9	0/9	0/5	0/5

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

Comment: One test animal was removed from the study on day 17 following signs of ill health.

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

9.2 Repeated Dose Toxicity (Notox, 1996e)

Species/strain: Rat/Wistar

Number/sex of animals: 20/sex (5sex/group)

Method of administration: Oral gavage; vehicle: distilled water.

Dose/Study duration: Control group: 0 mg/kg/day
Low-dose group: 50 mg/kg/day
Mid-dose group: 200 mg/kg/day
High-dose group: 1000 mg/kg/day for 28 consecutive days

Test method: EEC Directive 92/69/EEC B.7 Repeat Dose (28 days) Toxicity (Oral) 1992.

Clinical observations
No mortality occurred during the study period. There were no clinical signs of toxicity or behavioural changes over the observation period that were considered to be treatment related.

Clinical chemistry/Haematology
No treatment related clinical chemistry or haematological changes were detected.

A statistically significant decrease in white blood cells in females receiving 200 mg/kg/day, was considered to have arisen by chance as no dose relationship was seen and no concurrent changes were observed in the opposite sex.

Macroscopic findings/Organ weights/Histopathology
No treatment related macroscopic observations were made at necropsy.

No treatment related changes were detected in organ weights.

Microscopic examination revealed the forestomach of high-dose male and female rats

showed reactive changes which were characterised by parakeratosis and associated epithelial hyperplasia.

Comment
The treatment related changes observed in the forestomachs of high dose animals reflects an adaptive response to an irritant substance and not systemic toxicity.

Result
The NOAEL level for the notified chemical administered daily for 28 consecutive days is determined to be 1000 mg/kg/day.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Notox, 1996f)

Strains:	S. *typhimurium* TA1537, TA98, TA1535, TA100
Metabolic activation:	Liver fractions (S9) from rats pretreated with Aroclor 1254.
Concentration range:	Doses were based on a preliminary test with strain TA100. Triplicate plates were prepared for each bacterial strain and dose level, both with and without S9. Main Study: 0, 33, 100, 333, 1000 and 3330 μg/plate in all strains. Positive Controls: without S9 • sodium azide for TA1535 • 9-aminoacridine for TA1537 • daunomycin for TA98 • methylmethanesulfonate for TA100 with S9 • 2-aminoanthracene for all strains Negative control: dimethylsulfoxide.
Test method:	OECD TG 471
Comment:	All bacterial strains showed negative responses over the entire dose range. No toxicity of the test substance was observed. The notified chemical precipitated at and above 333 microgram/plate. Precipitation of the notified chemical was observed at the start and at the end of the incubation period at a concentration of 3330 microgram/plate in all tester strains.

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

9.3.2 Chromosomal Aberration Assay in Cultured Peripheral Human Lymphocytes (Notox, 1996g)

Cells: Human peripheral lymphocytes.

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

Dosing schedule:

• *Metabolic Activation*	• ***Experiment Number***	• *Test concentration (microgram/mL)*	• *Controls*
-S9	1	treatment time = 3 hours; harvest time = 24 hours; doses: 0*, 1*, 3*, 10* microgram/mL treatment time = 3 hours; harvest time = 48 hours; doses: 0*, 1*, 3*, 10* microgram/mL	Positive: MMC Negative: DMSO
+S9	2	treatment time = 3 hours; harvest time = 24 hours; doses: 0*, 1*, 3*, 10* microgram/mL treatment time = 3 hours; harvest time = 48 hours; doses: 0*, 1*, 3*, 10* microgram/mL	Positive: CP Negative: DMSO

MMC – mitomycin C: 0.2 microgram/mL expt 1, 24 hour harvest; 0.1 microgram/mL expt 1, 48 hour harvest
CP – cyclophosphamide: 15 microgram/mL
DMSO – dimethylsulphoxide
* - cultures selected for metaphase analysis

Test method: OECD TG 473

Comment: The test substance precipitated in the culture medium at a concentration of 10 microgram/mL. The number of cells with chromosomal aberrations found in the solvent control cultures were within the historical control range. The positive control chemicals produced statistically significant increases in the frequency of aberrant cells. The test substance did not induce statistically or biologically significant increases in the number of cells with chromosomal aberrations but reduced the mitotic indices to approximately 90% at the top dose.

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

9.4 Overall Assessment of Toxicological Data

The notified chemical was of very low acute oral toxicity in rats (LD50 > 2000 mg/kg) and low acute inhalation toxicity in rats (LC50 > 6.92 g/m^3). It was not a skin irritant in rabbits, was a slight to moderate eye irritant in rabbits and was not a skin sensitiser in guinea pigs. It was neither mutagenic in bacteria nor clastogenic in human lymphocytes in vitro. In a 28-day repeated dose oral toxicity study the NOAEL was 1000 mg/kg/day, the highest dose tested.

The notified chemical is determined not to be a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Test	*Species*	*Results*
96 hour acute	Carp	NOEC > 100 mg/L
48 hour acute	*Daphnia magna*	NOEC > 100 mg/L
96 hour growth inhibition	*Selenastrum capricornutum*	EbC50 = 18 mg/L
Respiration inhibition	Activated sludge	NOEC > 100 mg/L

* NOEC - no observable effect concentration

Carp were exposed under static conditions to aqueous dispersions of the notified chemical (nominally 10 or 100 mg/L) after separation of the water phase from undissolved material (Notox, 1996h).

Similarly, no effects were observed in daphnids under the same exposure conditions (Notox, 1996i).

Effects were noted in algae tested under these conditions. Undissolved particles (< 5 micron) present in the water phase at nominal concentrations of 32 mg/L or more inhibited cell growth by inducing aggregation of algal cells. Testing with the complete dispersion (no separation of the water phase) found complete inhibition of algal growth at 10 mg/L or more (Notox, 1996j).

No significant inhibition in respiration rate (oxygen consumption) of activated sludge was recorded at a nominal 100 mg/L. It appears that a complete dispersion was used, without separation of the water phase (Notox, 1996k).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

No releases to the aquatic environment are expected from normal use of the product containing the notified substance. Even in situations of large spills or discharges, the notified substance is not expected to reach concentrations that would be toxic to fish or crustacea because of its very low solubility. Algal growth may be inhibited following large spills or

discharges to the aquatic environment. No adverse effects are expected on aerobic microbial treatment plants.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard assessment

The notified chemical was of very low acute oral toxicity in rats (LD50 > 2000 mg/kg) and low acute inhalation toxicity in rats (LC50 > 6.92 g/m3). It was not a skin irritant in rabbits, was a slight to moderate eye irritant in rabbits and was not a skin sensitiser in guinea pigs. It was neither mutagenic in bacteria nor clastogenic in human lymphocytes in vitro. In a 28-day repeated dose oral toxicity study the NOAEL was 1000 mg/kg/day, the highest dose tested.

The notified chemical is determined not to be a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

Occupational Health and Safety

Waterside, warehouse and transport workers are unlikely to be exposed to the notified chemical unless the packaging is breached. Therefore the risk of eye irritation to these workers is low.

Machine operators and machine maintenance workers may be intermittently exposed to the notified chemical contained in the toner bottle when replacing the spent container, and during repair maintenance and cleaning of printers or photocopiers. Maintenance workers for printers or photocopiers may potentially come in contact with the notified chemical more often than other workers. Exposure is expected to be controlled through the design of the bottles and the printing or photocopying machines. Printer or photocopier maintenance personnel often wear cotton disposable gloves. Pre-packed bottles are sealed and worker exposure to the toner is minimised by the use of the replacement procedures recommended by the manufacturer. Therefore, the risk of eye irritation in any of these workers is low.

Contact with paper printed with toner containing the notified chemical is unlikely to result in dermal exposure, as it will be bound in the structure of the paper. It is the employers responsibility to maintain nuisance dust levels below the NOHSC exposure standard of 10 mg/m3 (NOHSC, 1995).

Public Health

The toner powder containing the notified chemical is largely consumed in the copying or printing processes. Unused residue toner powder is collected by service agents. There is negligible release of the powder from the plants where it is used. The likelihood of public exposure to the notified chemical through transport or industrial accidents is very low. Contact with the notified chemical as fixed onto printed paper or other material is not likely to result in its transfer to the skin. If public contact with the notified chemical occurs it is most likely to be dermal, ocular or respiratory contact of an infrequent and transient nature.

The very low likelihood of public contact with the notified chemical and the toxicological profile of the notified chemical suggest that it will not pose a significant hazard to public health when used as proposed.

13. RECOMMENDATIONS

Control Measures

Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in the imported toner product:
  - maintenance workers should wear cotton disposable gloves

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- Employers should ensure that nuisance dust levels are maintained below the NOHSC exposure standard of 10 mg/m3 (NOHSC, 1995).

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

13.1 Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

14. MATERIAL SAFETY DATA SHEET

The MSDS for toner products containing 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. REFERENCES

National Occupational Health and Safety Commission (1994) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1995) Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment, [NOHSC:1003(1995)], Exposure Standards for Atmospheric Contaminants in the Occupational Environment: Guidance Note and National Exposure Standards, Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. Australian Government Publishing Service, Canberra.

Notox (1996a) Assessment of Acute Oral Toxicity with SX9509 in the Rat. Project No. 164194, Notox B V, The Netherlands (unpublished report submitted by Océ-Australia Limited).

Notox (1996b) Primary Skin Irritation/Corrosion Study with SX9509 in the Rabbit (4-Hour Semi-Occlusive Application). Project No. 164216, Notox B V, The Netherlands (unpublished report submitted by Océ-Australia Limited).

Notox (1996c) Acute Eye Irritation/Corrosion Study with SX9509 in the Rabbit. Project No. 164227, Notox B V, The Netherlands (unpublished report submitted by Océ-Australia Limited).

Notox (1996d) Assessment of Contact Hypersensitivity to SX9509 in the Albino Guinea Pig (Maximization Test). Project No. 164238, Notox B V, The Netherlands (unpublished report submitted by Océ-Australia Limited).

Notox (1996e) Subacute 28-Day Oral Toxicity with SX9509 by Daily Gavage in the Rat. Project No. 160785/160774, Notox B V, The Netherlands (unpublished report submitted by Océ-Australia Limited).

Notox (1996f) Evaluation of the Mutagenicity of SX9509 in the Salmonella tyhimurium Reverse Mutation Assay (with Independent Repeat). Project No. 164249, Notox B V, The Netherlands (unpublished report submitted by Océ-Australia Limited).

Notox (1996g) Evaluation of the Ability of SX9509 to Induce Chromosome Aberrations in Cultured Peripheral Human Lymphocytes (with Independent Repeat). Project No. 164251, Notox B V, The Netherlands (unpublished report submitted by Océ-Australia Limited).

Notox (1996h) 96-hour Acute Toxicity Study in Carp with SX9509. Project No. 164262, Notox B V, The Netherlands (unpublished report submitted by Océ-Australia Limited).

Notox (1996i) Acute Toxicity Study in *Daphnia magna* with SX9509. Project No. 164273, Notox B V, The Netherlands (unpublished report submitted by Océ-Australia Limited).

Notox (1996j) Fresh Water Algal Growth Inhibition Test with SX9509. Project No. 164284, Notox B V, The Netherlands (unpublished report submitted by Océ-Australia Limited).

Notox (1996k) Activated Sludge Respiration Inhibition Test with SX9509. Project No. 164295, Notox B V, The Netherlands (unpublished report submitted by Océ-Australia Limited).

TNO (1996) Acute (4-hour) Inhalation Study with SX9509 in Rats. Project No. 164205, TNO Nutrition and Food Research Institute, The Netherlands (unpublished report submitted by Océ-Australia Limited).

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

Draize, J. H., Woodward, G., Calvery, H. O. (1944) Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes, J. Pharmacol. Exp. Ther. 82 : 377-390.

Draize J. H. (1959) Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the US, 49 : 2-56.