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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Duasyn Direct Black HEF-SF

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

Duasyn Direct Black HEF-SF

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Clariant (Australia) Pty Ltd (ABN 30 069 435 552) of 675-685 Warrigal Road Chadstone VIC 3148
Moore Business Systems Australia Ltd (ABN 11 008 430 662) of 3-5 Maloney Drive Wodonga VIC 3690

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

Part B: Chemical Name, Other Names, CAS Number, Molecular and Structural Formulae, Molecular Weight, Spectral Data, Purity, Impurities (Hazardous/Non-hazardous), Additives/Adjuvants, Use, Import Volume, and Release to Environment from Use.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

Particle Size, Acute Inhalation Toxicity, and Algal Growth Inhibition Test.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
Not applicable

NOTIFICATION IN OTHER COUNTRIES
European Union, USA, Canada and Japan (1996)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Duasyn Direct Black HEF-SF, Duasyn Direct Black HEF-SF VP332, Duasyn Direkt Schwarz HEF-SF VP332, CA 953, and Scitex 3600 Black Ink (<5% notified chemical)

3. COMPOSITION

DEGREE OF PURITY **Non-Confidential**
Up to 80%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
Imported

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	≤10	≤10	≤10	≤10	≤10

USE **Non-Confidential**
A component of ink products for use in commercial printing equipment and office inkjet printers.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, Transport and Storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS **Non-Confidential**
Clariant (Australia) Pty Ltd & Moore Business Systems Australia Ltd

TRANSPORTATION AND PACKAGING
The ink products containing the notified chemical will be transported by road in individually packaged printer cartridges and in 20 and 208 L drums. These will be enclosed in either multi-pack fiberboard boxes (printer cartridges) or palletised (drums).

5.2. Operation Description

The notified chemical will enter Australia only as a component of ready-to-use ink products such as Scitex 3600 Black Ink for use in commercial printing equipment. Ink cartridges for use in office inkjet printers may be imported in the future. No formulating, packaging, filling, or refilling of cartridges or containers will occur in Australia.

For use of the Scitex aqueous ink product, printing operators at the industrial printing site of the Moore Business Systems will be involved in connection and disconnection of transfer piping from ink containers to printing machines.

When replacing ink cartridges, office staff will follow replacement procedures recommended by the manufacturer. This involves removing the seal tape and inserting the cartridge into inkjet printers. Empty cartridges are disposed of with normal office waste.

5.3. Release

RELEASE OF CHEMICAL AT SITE
No release is expected as formulation of the ink containing the notified chemical will not take place in Australia.

5.4. Disposal

The total import volume of the notified chemical will ultimately be disposed of either in landfill or be incinerated.

6. PHYSICAL AND CHEMICAL PROPERTIES

Test reports were provided in German. English translations were available only for selected sections, pages and some report summaries, therefore assessment of the test methods, conditions and results was limited.

APPEARANCE AT 20°C AND 101.3 kPa	Black, odourless powder
MELTING POINT	>287.5°C

METHOD	EC Directive 92/69/EEC A.1 Melting/Freezing Temperature
Remarks	No melting was observed before the onset of auto-ignition, namely 288 °C.
TEST FACILITY	Cassella Aktiengesellschaft, Analytical and Physical Department, Germany (1992b)

BOILING POINT	>700°C

METHOD A minimum value for the boiling point was estimated using the Meissner's method detailed in the Handbook of Chemical Property Estimation Methods, Environmental Behaviour of Organic Compounds.
Remarks Full test report was not provided.
The notified chemical cannot boil without decomposing at 101.3 kPa.
TEST FACILITY Cassella Aktiengesellschaft, Analytical and Physical Department, Germany (1992c)

DENSITY 1499 kg/m^3 at 20°C

METHOD Pycnometer method, decane as the displacement liquid.
TEST FACILITY Cassella Aktiengesellschaft, Analytical and Physical Department, Germany (1992d)

VAPOUR PRESSURE < $2x10^{-24}$ kPa at 25°C

METHOD A maximum value for the vapour pressure was estimated using the Meissner's method detailed in the Handbook of Chemical Property Estimation Methods, Environmental Behaviour of Organic Compounds.
Remarks Full test report was not provided.
TEST FACILITY Cassella Aktiengesellschaft, Analytical and Physical Department, Germany (1992c)

WATER SOLUBILITY >350 g/L at 20°C

METHOD EC Directive 92/69/EEC A.6 Water Solubility.
Remarks The result was from the preliminary test. The flask method was not carried out due to the high viscosity of the test solution. A supersaturated solution could not be prepared as the solution became lumpy and difficult to homogenize at high concentrations.
TEST FACILITY Cassella Aktiengesellschaft, Analytical and Physical Department, Germany (1992e)

HYDROLYSIS AS A FUNCTION OF pH Slightly decomposed by hydrolysis

METHOD EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.
Remarks The preliminary test showed that the concentration of the notified chemical did not decrease by more than 10% at any pH in the 5 day test period. The chemical contains no groups generally considered to be hydrolysable.
TEST FACILITY Cassella Aktiengesellschaft, Analytical and Physical Department, Germany (1992f)

PARTITION COEFFICIENT (n-octanol/water) log Pow = -4.06 at 22.8 °C-24.3°C

METHOD EC Directive 92/69/EEC A.8 Partition Coefficient
Remarks A stock solution of the notified chemical (1.057 g in 100 mL n-octanol saturated water) was prepared. Vials containing varying quantities of the stock solution, water and octanol were shaken for 2.25 h followed by separation of the phases by centrifugation and filtration. The solubility of the notified chemical was determined in both octanol and water by spectrophotometry at 620 nm and these values were used to calculate the partition coefficient.
TEST FACILITY Cassella Aktiengesellschaft, Analytical and Physical Department, Germany (1992g)

ADSORPTION/DESORPTION Not determined.

METHOD However, a summary of a study measuring adsorption onto sewage sludge was provided. The notified chemical (5 g) was added to a standard moist sewage solution (~30 g in 100 mL water) and mixed for 2 h at 25ºC. The resulting suspension was filtered and the dye content was determined photometrically. The notifier indicates that 80.8% of the added dye was adsorbed onto the sewage sludge.
Remarks Full test report was not provided.
TEST FACILITY Cassella Aktiengesellschaft, Analytical and Physical Department, Germany (1994a)

DISSOCIATION CONSTANT Not determined.

Remarks The preliminary test by titration confirmed that there was an overlapping of pKa values of individual chemical groups. The notified chemical is fully dissociated as the sulfonate groups are strongly acidic.
TEST FACILITY Cassella Aktiengesellschaft, Analytical and Physical Department, Germany (1994b)

PARTICLE SIZE No data available

Remarks The notified chemical is a powder but will not be imported as technical grade material. It will only be imported in formulated liquid ink products.

FLASH POINT Not applicable

Remarks Test not conducted on a solid.

FLAMMABILITY LIMITS Not highly flammable

METHOD EC Directive 92/69/EEC A.10 Flammability (Solids)
Remarks The notified chemical showed in all six ignition tests only faint smouldering but no flaming and burning.
TEST FACILITY Cassella Aktiengesellschaft, Analytical and Physical Department, Germany (1992h)

AUTOIGNITION TEMPERATURE 288ºC

METHOD 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids
Remarks The temperature of the notified chemical reached 400ºC at an oven temperature of 288ºC.
TEST FACILITY Cassella Aktiengesellschaft, Analytical and Physical Department, Germany (1992i)

EXPLOSIVE PROPERTIES Not explosive

METHOD EC Directive 92/69/EEC A.14 Explosive Properties.
Remarks None of the individual tests produced sparks or explosions.
TEST FACILITY Cassella Aktiengesellschaft, Analytical and Physical Department, Germany (1992j)

REACTIVITY – OXIDIZING PROPERTIES Not determined

Remarks Test not conducted as it could be predicted based on the chemical structure that the notified chemical cannot react exothermically with flammable material and has no oxidizing properties.
TEST FACILITY Cassella Aktiengesellschaft, Analytical and Physical Department, Germany (1992k)

SURFACE TENSION 72.1 mN/m and 73.1 mN/m at 20ºC

Remarks The above values were determined with an interfacial tensiometer using a solution containing the notified chemical at a concentration of 10.054 g/L and 1.005 g/L, respectively. The notified chemical is not surface active.
TEST FACILITY Cassella Aktiengesellschaft, Analytical and Physical Department, Germany (1992l)

FAT SOLUBILITY Insoluble

METHOD EC Directive 92/69/EEC A.7 Fat Solubility of Solid
Remarks Spectrophotometry at 620 nm. Test solutions were below the detection limit.
TEST FACILITY Cassella Aktiengesellschaft, Analytical and Physical Department, Germany (1992m)

7. TOXICOLOGICAL INVESTIGATIONS

7.1. Acute toxicity – oral

TEST SUBSTANCE Duasyn Direct Black HEF-SF VP332 (notified chemical)

METHOD: OECD TG 401 Acute Oral Toxicity – Limit Test
EC Directive 84/449/EEC B.1 Acute Toxicity (Oral) – Limit Test.

Species/Strain: Rat/Sprague-Dawley
Vehicle: Arachis oil BP
Remarks - Method:

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 females	2000	3
2	5 males	2000	0

LD50: > 2000 mg/kg bw (males), < 2000 mg/kg bw (females)
Signs of Toxicity: Hunched posture, lethargy, ptosis, and decreased respiratory rate were noted in one female six days post dosing. This animal was found dead on day 7. All treated females show black staining of the general body fur.
Effects in Organs: Red lungs, dark liver, and dark kidney in females that died during the study.
Remarks - Results: All treated males appeared normal through the study period.

CONCLUSION: The notified chemical is harmful via the oral route.

TEST FACILITY: Safepharm Laboratories Limited, UK (1991a).

7.2. Acute toxicity – dermal

TEST SUBSTANCE: Duasyn Direct Black HEF-SF VP332 (notified chemical)

METHOD: OECD TG 402 Acute Dermal Toxicity – Limit Test
EC Directive 84/449/EEC B.3 Acute Toxicity (Dermal) – Limit Test.

Species/Strain: Rat/Sprague-Dawley
Vehicle: Distilled water
Type of dressing: Semi-occlusive.
Remarks - Method:

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 females	2000	0
2	5 males	2000	0

LD50: > 2000 mg/kg bw
Signs of Toxicity - Local: Black staining at treatment site and the fur of all animals.
Signs of Toxicity - Systemic: None
Effects in Organs: None
Remarks - Results: Staining of fur did not interfere with evaluation of responses.

CONCLUSION: The notified chemical is of low toxicity via the dermal route.

TEST FACILITY: Safepharm Laboratories Limited, UK (1991b).

7.3. Irritation – skin

TEST SUBSTANCE: Duasyn Direct Black HEF-SF VP332 (notified chemical)

METHOD: OECD TG 404 Acute Dermal Irritation/Corrosion.

EC Directive 84/449/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	Three
Vehicle	Distilled water
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks – Method	

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	1	24 hours	0
Oedema	0	0	0	1	1 hour	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks – Results: Black staining at all treated sites. Primary irritation index is 0.25.

CONCLUSION: The notified chemical is slightly irritating to skin.

TEST FACILITY: Safepharm Laboratories Limited, UK(1991c).

7.4. Irritation – eye

TEST SUBSTANCE: Duasyn Direct Black HEF-SF VP332 (notified chemical)

METHOD: OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 84/449/EEC B.5 Acute Toxicity (Eye Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	Three
Observation Period	14 days
Remarks - Method	

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Conjunctiva: redness	1.3	1.3	1.7	2	7 days	0
Conjunctiva: chemosis	1.3	1.3	1.3	2	7 days	0
Conjunctiva: discharge	0	1.3	1	3	48 hours	0
Corneal opacity	Cannot evaluate			--	--	--
Iridial inflammation	Staining precluded complete evaluation			1 (one animal only)	1 hour	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks – Results: Black staining at all treated sites precluded assessment of adverse corneal effects throughout the study and assessment of the iridial effects in two animals at some of the observations. The staining persisted in all animals to the end of the 14-day observation period. All treated eyes showed slight to moderate conjunctival swelling and severe discharge 1 hour after treatment. Sloughing of the corneal epithelium was noted in one treated eye at the 24-hour observation.

CONCLUSION: The notified chemical is irritating to the eye.

TEST FACILITY Safepharm Laboratories Limited, UK (1991d).

7.5. Skin sensitisation

TEST SUBSTANCE Duasyn Direct Black HEF-SF VP332 (notified chemical)

METHOD OECD TG 406 Skin Sensitisation – Maximisation Test
EC Directive 84/449/EEC B.6 Skin Sensitisation
Species/Strain Guinea pig/Dunkin-Hartley
PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: 1% in distilled water
topical: 50% in arachis oil BP
MAIN STUDY
Number of Animals Test Group: 20 Control Group: 10
INDUCTION PHASE Induction Concentration:
intradermal injection 1% in distilled water
topical application 50% in arachis oil BP
Signs of Irritation Black staining precluded evaluation.
CHALLENGE PHASE
1st challenge topical application: 50% in arachis oil BP
Remarks - Method

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	50% in arachis oil BP	0	0
Control Group	50% in arachis oil BP	0	0

Remarks - Results Black staining was noted. The staining prevented accurate evaluation of erythema during induction, but did not affect evaluation of skin responses during topical challenge.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY Safepharm Laboratories Limited, UK (1991e).

7.6. Repeat dose toxicity

TEST SUBSTANCE Duasyn Direct Black HEF-SF VP332 (notified chemical)

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
EC Directive84/449/EEC B.7 Repeated Dose (28 Days) Oral Toxicity
Species/Strain Rat/Sprague-Dawley CD
Route of Administration Oral – gavage
Exposure Information Total exposure days: 28 days
Dose regimen: daily
Post-exposure observation period: Immediately pre-dosing, 1 and 5 hours after dosing.
Vehicle Distilled water
Remarks - Method

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
1 (control)	5 per sex	0	0

2 (low)	5 per sex	15	0
3 (intermediate)	5 per sex	150	0
4 (high)	5 per sex	1000	0

Mortality and Time to Death
No treatment-related deaths.

Clinical Observations
No observable signs of toxicity were noted. Black staining of the fur and around the mouth was detected in high dose animals from day 6 onwards. Dark faeces observed in intermediate and high dose animals from day 3 onwards. Body weight gain and food consumption was comparable with controls in all treatment groups.

Laboratory Findings
Haematology
High dose animals showed evidence of macrocytic hypochromic anaemia as evidenced by decreased haemoglobin concentration, erythrocyte counts and mean corpuscular haemoglobin concentration (males only), along with an increase in mean corpuscular volume. A similar but less pronounced effect was demonstrated in intermediate dose animals. No treatment-related changes were apparent in low dose animals.

Clinical Chemistry
High dose females showed a marked reduction in plasma potassium concentration together with a slight, but statistically significant reduction in plasma chloride. High dose animals of both sexes also exhibited an increase in inorganic phosphorus. These changes are probably indicative of a treatment-related effect on kidney function. No treatment related changes were detected in intermediate or low dose animals.

High dose males demonstrated a statistically significant decrease in total plasma proteins and high dose females showed an elevation in albumin/globulin ratio. However, these values were within historical values and considered fortuitous.

Effects in Organs
Organ Weights
High dose animals showed a statistically significant increase in spleen and adrenal weights (males only) compared to controls, both absolute and relative to bodyweight. Adrenal weights of several individuals were abnormally high for rats of this strain and age. No treatment-related changes were detected in the remaining groups.

Histopathology
Treatment-related changes were observed in the adrenal glands, spleen, kidneys and lymph nodes such as increased severity of cortical cell vacuolation (high dose males) and extramedullary haemopoiesis (both sexes), accumulation of haemosiderin (intermediate and high dose females), pigments in kidney tubular epithelium (both sexes), and pigments in cervical and mesenteric lymph nodes (high dose females). A number of high dose female rats also exhibited focal epithelial hypertrophy/hyperplasia of the renal papilla.

Remarks – Results

CONCLUSION
The No Observed Effect Level (NOEL) was established as 15 mg/kg bw/day in this study, based on effects on the haematopoietic system at 150 mg/kg/day.

TEST FACILITY — Safepharm Laboratories Limited, UK (1991f).

7.7. Genotoxicity – bacteria

(based on results of the two test reports submitted)

TEST SUBSTANCE — Duasyn Direct Black HEF-SF VP332 (notified chemical)

METHOD — OECD TG 471 Bacterial Reverse Mutation Test – "Ames test".
EC Directive 84/449/EEC B.14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure

Species/Strain — *S. typhimurium*: TA1535, TA1537, TA1538, TA98, TA100

	E. coli: WP2 uvrA$^-$
Metabolic Activation System	Hamster liver microsome S9 fraction
Concentration Range in Main Test	a) With metabolic activation: 0, 8, 40, 200, 1000, 5000 µg/plate. b) Without metabolic activation: 0, 8, 40, 200, 1000, 5000 µg/plate.
Vehicle	Sterile distilled water
Remarks - Method	

RESULTS

Remarks - Results	No toxicity and no significant increase in the numbers of revertant colonies of bacteria were recorded in both test reports for any of the strains of *Salmonella* or *E. coli* used, at any dose levels either with or without metabolic activation. A precipitate of the test substance was noted at 5000 µg/plate in one test report, but this did not affect scoring of the agar plates.

CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the tests.
TEST FACILITY	Safepharm Laboratories Limited, UK (1991g & h).

7.8. Genotoxicity – in vitro

TEST SUBSTANCE	Duasyn Direct Black HEF-SF VP332 (notified chemical)
METHOD	OECD TG 473 In vitro Mammalian Chromosomal Aberration Test EC Directive 84/449/EEC B.10 In vitro Mammalian Chromosomal Aberration Test
Cell Type/Cell Line	Chinese hamster ovary (CHO-K1 BH4)
Metabolic Activation System	Rat liver microsome S9 fraction.
Vehicle	Ham's F12 medium + 10% foetal bovine serum and antibiotics
Remarks - Method	

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Present			
Test 1	156.25, 312.5, 625 and 1250	4 hours	12 hours
Test 2	156.25, 312.5, 625 and 1250	4 hours	20 hours
Absent			
Test 1	156.25, 312.5, 625 and 1250	12 hours	12 hours

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:* *Cytotoxicity in PreliminaryTest*	*Genotoxic Effect*
Present		
Test 1	1250	---
Test 2	1250	---
Absent		
Test 1	2500	625

Remarks - Results	Cultures showed a total absence of metaphase cells at and above 2500 µg/mL both with and without S9 activation. The test substance induced no significant increase in the numbers of polyploid cells at any dose levels in any of the treatment cases. A statistically significant increase in the frequency of cells with aberrations (including gaps) was seen at one dose level only (625 µg/mL, 12 hour exposure without S9). There was no dose-response relationship and the frequency was within historical controls for CHO cells.

CONCLUSION The notified chemical was not clastogenic to CHO cells treated in vitro under the conditions of the test.

TEST FACILITY Safepharm Laboratories Limited, UK (1991i).

7.9. Genotoxicity – in vivo

TEST SUBSTANCE Duasyn Direct Black HEF-SF VP332 (notified chemical)

METHOD OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
EC Directive 84/449/EEC B.12 Mutagenicity Mammalian Erythrocyte Micronucleus Test.

Species/Strain Mouse/Albino CD1
Route of Administration Oral – gavage
Vehicle Arachis oil BP
Remarks - Method

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
Test substance	5 per sex	3000	24, 48, and 72
Vehicle control	5 per sex	0	24, 48, and 72
Positive control	5 per sex	50 (CP)	24

CP=cyclophosphamide

RESULTS

Doses Producing Toxicity 3000 mg/kg bw
Genotoxic Effects When compared to vehicle control group, there was a significant change in the NCE/PCE (normochromatic/polychromatic erythrocytes) ratio in the 72-hour test substance group, but no significant increase in either NCE or PCE was observed in any test substance groups.
Remarks - Results One premature death was recorded in the 24-hour test substance group.

CONCLUSION The notified chemical was not genotoxic under the conditions of this in vivo micronucleus test.

TEST FACILITY Safepharm Laboratories Limited, UK (1991j).

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE Duasyn Direct Black HEF-SF (notified chemical)

METHOD OECD TG 301 B Ready Biodegradability: CO2 Evolution Test

Exposure Period 28 days
Remarks - Method Activated sludge was mixed with the test substance to give final test concentrations of 10 and 20 mg/L and with the standard material, sodium acetate at a concentration of 20 mg/L. The study was carried out in darkness at 21 °C.

RESULTS

Test substance		*sodium acetate*	
Day	*Mean % degradation*	*Day*	*% degradation*
14	21.5	14	82
28	38	28	90

Remarks - Results	The sodium acetate standard attained 90% biodegradation after 28 days, indicating the test conditions were valid. After 28 days, the mean biodegradation of the test substance was determined to be 38% (44% at 10 mg/L and 32% at 20 mg/L).
CONCLUSION	The notified chemical is not considered to be readily biodegradable under the conditions of the test.
TEST FACILITY	Laboratorium Für Angewandte Biologie, Sarstedt, Germany (1991a)

8.1.2. Bioaccumulation

Data regarding the bioaccumulation potential of the notified chemical were not provided. The high molecular weight, high water solubility and low fat solubility of the notified chemical suggest that it is unlikely to cross biological membranes and bioaccumulate (Connell 1990).

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Duasyn Direct Black HEF-SF (notified chemical)
METHOD	OECD TG 203 Fish, Acute Toxicity Test
Species	Zebra fish (*Branchydanio rerio*)
Analysis	Spectrophotometry at 0 and 96 h
Exposure Period	96 hours
RESULTS	

Concentration mg/L Nominal	*Number of Fish*	*% Mortality*			
		24h	*48h*	*72h*	*96h*
0	10	0	0	0	0
32	10	0	0	0	0
58	10	0	0	20	20
100	10	0	60	80	80
180	10	0	80	90	90
320	10	10	60	90	90
580	10	50	100	100	100

LC50	83 mg/L at 96 hours (95% confidence level of 64-103 mg/L).
NOEC (or LOEC)	Not specified.
Remarks – Results	The results of the definitive study showed that no mortalities were observed in the test vessels with less than 32 mg/L of test substance. The authors indicate that all test vessels were black coloured and not transparent. After 96 h, 20, 80, 90, 90, and 100% mortality was observed at test concentrations of 58, 100, 180, 320 and 580 mg/L of the notified substance, respectively. The 96-hour EC_{50} for the notified chemical to *Oncorhynchus mykiss* is 83 mg/L based on nominal concentrations.
CONCLUSION	The ecotoxicity data indicate the notified chemical is slightly toxic to fish.
TEST FACILITY	Laboratorium Für Angewandte Biologie, Sarstedt, Germany (1991b)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Duasyn Direct Black HEF-SF (notified chemical)
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test
Species	*Daphnia magna*

Exposure Period	48 hours

RESULTS

Concentration mg/L		*Number of D. magna*	*% Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	0	20	0	0
10	11.3	20	0	5
18	20.8	20	0	20
32	38.7	20	0	20
58	66.6	20	0	35
100	122.9	20	0*	30
180	225.3	20	0*	90
320	369.2	20	60*	100
580	676.3	20	N.B.	N.B.
1000	1168.7	20	N.B.	N.B.

N.B. = not assignable, * = The number of daphnids immobilised could not be determined due to black colouration in the test vessel.

LC50	76 mg/L at 48 hours (95% confidence level of 57-101 mg/L).
NOEC (or LOEC)	Not determined
Remarks - Results	The immobilisation tests with *Daphnia* were performed in quadruplicate using 10 daphnids per flask with observations performed at 24 and 48 hours. The author indicates that it was difficult to determine the number of immobilised daphnids present due to black colouration in each test vessel during the first 24 h. The 48-hour EC_{50} for the notified chemical to *Daphnia magna* is 76 mg/L as determined by probit analysis.
CONCLUSION	The ecotoxicity data indicates the notified chemical is slightly toxic to daphnia.
TEST FACILITY	Laboratorium Für Angewandte Biologie, Sarstedt, Germany (1991b)

8.2.3. Algal growth inhibition test

Remarks	An algal growth inhibition test was not conducted. The notifier indicates that in screening test with similar dyes algae died because all light is absorbed by the test substance.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will enter environmental compartments indirectly by disposal of waste paper (for recycling, to landfill or for incineration) and by direct release from discarded cartridges and containers at landfill sites. Some waste paper may be disposed of directly to landfill with the notified chemical strongly bound to the paper. It is anticipated that prolonged residence in an active landfill environment would eventually degrade the notified chemical. Incineration of waste paper will destroy the compound with the generation of water vapour and oxides of carbon, nitrogen and sulphur. In addition to landfill, some of the ink printed on paper will enter the paper recycling process. During such processes, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. These agents enhance fibre separation, ink detachment from the fibres, pulp brightness and the whiteness of paper. De-inking wastes are expected to go to trade waste sewers. Trade sources estimate the washing process will recover 30-60% of the total amount of ink and therefore at least 30% of the notified chemical in the recycled paper will be disposed of with sludge in landfill.

Based on the import volume, method of packaging and low concentration of the notified chemical in the ink product, release of the notified chemical to the environment is expected to be low but widespread. Waste from the recycling process includes sludge which is dried and disposed of to landfill, and little of the notified chemical is expected to partition to the supernatant water which is released to the sewer.

Although it is not considered to be readily biodegradable, significant biodegradation of the notified chemical is expected to occur. The low octanol-water partition coefficient and high water solubility indicate the notified chemical will be predominantly distributed in water, where it will become diluted and dispersed and eventually partition to sediment. Adsorption data indicate a rapid partitioning.

9.1.2. Environment – effects assessment

The notified chemical is slightly toxic to fish and daphnia. However, there will be limited release to water. In addition, bioaccumulation is not expected due to the low log P_{ow}, indicating low lipid solubility, and large molecular weight (≥ 650 g/mol). These will inhibit the notified chemical passing through cell membranes.

9.1.3. Environment – risk characterisation

The notified chemical will be used as an ingredient of printing ink formulations, and most will eventually be disposed of in landfill. The compound is not readily biodegradable (38% over 28 days), has a low partition coefficient of –4 and a high water solubility of >350 g/L, all indicating that most of the chemical would eventually partition to water. However, the notifier has shown that when mixed with moist sewage sludge, less than 20% of the added dye remains in the aqueous phase after 2 hours. Therefore, the small quantity released to sewer is expected to associate with sewage sludge prior to release to receiving waters.

Considering all information above there is a minimal risk to the environment when the notified chemical is used at low concentrations of <5% in ink products and in the manner indicated by the notifier.

9.2. Human health

9.2.1. Occupational health and safety

9.2.1.1 OCCUPATIONAL EXPOSURE ASSESSMENT

Waterside, warehouse and transport personnel will be involved in handling, storage and transport of individually packaged ink cartridges (which are enclosed in multi-pack fibreboard boxes) and palletised drums of the printing ink. The notifier indicates that due to widespread acceptance and usage of inkjet printers as part of office equipment, the number of workers potentially exposed to such packaged ink products will be large. However, it is expected that direct exposure of workers belonging to this category is unlikely unless packaging is damaged.

Some thousands of office workers are also expected to be potentially exposed to the printer ink and the notified chemical (probably less than 1 hour per person per year) when they are involved in storage of packaged ink cartridges, in replacement of cartridges, in handling of printed paper and disposal of empty cartridges. However, ink products are enclosed within sealed cartridges from which the office workers remove seal tapes without contacting the printer ink. Spillage is not expected to occur as the ink products are fully enclosed in cartridges. For routine handling of ink cartridges, the following precautions are recommended: (1) Avoid contact of ink with the eyes, skin and clothing; (2) Wash hands after use with soap and cold water. Office inkjet printers should be positioned in well-ventilated areas to avoid accumulation of any dusts, gases or fumes.

It is estimated that up to one hundred maintenance workers will be exposed to the ink containing the notified chemical, depending on the market penetration of the new dye Duasyn Direct Black HEF-SF. The maintenance will involve repairs/servicing and cleaning of office equipment with duration of exposure expected to be >4 hours per working day. It is recommended that workers use adequate personal protection equipment (including disposable gloves) and good work practices to minimise skin contact.

Use of the aqueous ink product Scitex 3600 Black Ink in commercial printing equipment will involve up to 6 printing operators with potential exposure of 2-4 hours per working day. The printing operators will be also involved in connection and disconnection of transfer piping from ink containers to printing machines. To prevent long-term skin staining caused by the ink, it is recommended that personal protective equipment such as safety glasses, plastic or rubber gloves and industrial standard work-wear with rubber aprons should be used at all times for any printing tasks.

The notifier indicates that no specific training is required to handle ink products containing the notified chemical. Normal practices in handling and use of ink products are applicable and instructions on replacement of ink cartridges are adequate to prevent exposure to the ink. The MSDS for the ink products is readily accessible.

9.2.2. Public health

It is expected that during transport, storage and occupational use of inkjet cartridges/drums, exposure of the general public to the notified chemical will be low, except in the event of accident spillages. These should be contained and absorbed with liquid-binding material (sand, polypads or suitable absorbent material) and placed into appropriate labelled containers. Spill areas should be rinsed thoroughly with a solution of soap and water. Protective clothing should be worn against splashes during clean-up. Waste should be disposed of according to Federal, State, and local hazardous waste disposal regulations.

Public exposure to the notified chemical will occur from contact with printed media containing the notified chemical and the replacement of spent cartridges/drums in office and commercial printers. Replacing spent cartridges involves the removal of a tape seal prior to installation. Any exposure is thus likely to be low, mainly via dermal and possibly via ocular exposure.

9.2.3. Human health - effects assessment

9.2.3.1 SUMMARY OF TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 <2000 mg/kg bw (female)	Harmful
Rat, acute dermal LD50 >2000 mg/kg bw	Low toxicity
Acute inhalation	No data available
Rabbit, skin irritation	Slightly irritating
Rabbit, eye irritation	Irritating
Guinea pig, skin sensitisation - adjuvant test	No evidence of sensitisation.
Rat, Repeat Dose Oral Toxicity – 28 Days.	NOEL = 15 mg/kg bw
Genotoxicity - bacterial reverse mutation	Non mutagenic
Genotoxicity – in vitro Chromosomal Aberration Test	Non genotoxic
Genotoxicity – in vivo Micronucleus Test	Non genotoxic

9.2.3.2 DISCUSSION

The notified chemical is harmful by the oral route, with the acute oral LD50 < 2000 mg/kg in female Sprague-Dawley rat. All three tested females were found dead with necropsy revealing abnormally red lungs, dark liver and an isolated incident of dark kidneys. Signs of toxicity noted in one female were hunched posture, lethargy, ptosis and decreased respiratory rate. Females also showed black staining of the general body fur. In contrast, all males appeared normal throughout the study period.

The acute dermal LD50 of the notified chemical in the Sprague-Dawley rat was found to be >2000 mg/kg. There were no deaths and no signs of systemic toxicity or skin irritation noted although all animals showed black staining of the fur and at the treatment site.

The notified chemical was classified as a mild irritant to the skin and an irritant to eyes. A 4-hour exposure of the intact skin of three rabbits to the notified chemical (moistened with distilled water) produced a slight erythema and slight oedema with a primary irritation index of 0.25. In the eye irritation test, black staining at all treated sites precluded assessment of corneal

opacity throughout the study and of the iridial effects in two treated groups at some of the observations. It was noted that all treated eyes showed slight to moderate conjunctival swelling and severe discharge one hour after treatment. Moderate conjunctival irritation was also observed in all treated eyes after 24 hours and in one treated eye after 48 hours. Iridial inflammation and sloughing of the corneal epithelium was noted in one treated eye one hour and 24 hours after treatment respectively.

The notified chemical was determined to be a non-sensitiser when tested on guinea pigs.

A repeat dose oral toxicity study indicated a NOEL of 15 mg/kg bw/day in rats, based on any haematological changes such as the presence of a haemolytic anaemia and increased amounts of haemosiderin. Haematological determinations in animals treated with 1000 mg/kg/day showed effects consistent with a macrocytic hypochromic anaemia. A similar but less severe effect was also demonstrated in animals treated with 150 mg/kg/day. In view of the increase in spleen weight (which was probably caused by the increase in extramedullary haemopoiesis noted histopathologically), and because an increased amount of haemosiderin was found in the spleen, it seems likely that the anaemia was haemolytic in nature. No toxicologically significant changes in any of the measured parameters were apparent in animals treated with 15mg/kg/day.

In vitro (including bacteria) and in vivo studies indicated no experimental evidence for genotoxicity of the notified chemical. The increase in the frequency of CHO cells with aberrations (including gaps) at 625 µg/mL after 12-hour exposure without metabolic activation was considered not to be toxicologically significant, therefore not indicative of clastogenic activity.

9.2.4. Human health – risk characterisation

9.2.4.1 OCCUPATIONAL HEALTH AND SAFETY

Waterside, warehouse and transport personnel are unlikely to be exposed to the notified chemical unless the packaging is damaged. In addition, the imported product (Scitex 3600 Black Ink) contains the notified chemical Duasyn Direct Black HEF-SF at a low level of <5%. On this basis, the occupational health risk encountered by these workers is determined to be low.

Due to widespread acceptance and usage of inkjet printers as part of office equipment, some thousands of office workers will be potentially exposed to the notified chemical, mainly via dermal and possibly ocular exposure. The notifier indicates that the design of ink cartridges requires a seal-tape to be removed before the cartridge is used and thus no direct skin contact to the ink is expected. Instructions on replacement procedures presented with the cartridges, together with good work practices and low concentration of chemical in the product are considered adequate for 'untrained' office staff to be able to replace and dispose of empty ink cartridges without any significant health risk. The notified chemical once bound to paper during printing is unlikely to be available for absorption during human contact.

Based on the available toxicological data, the notified chemical is harmful on oral ingestion and can cause irritation and staining of the eyes. Workers are advised to avoid skin and eye contact with the ink and observe general hygiene practices such as washing of hands after handling the cartridges. Although inhalation exposure to the ink is unlikely, inkjet printers should be positioned in well-ventilated areas to avoid accumulation of any dusts, gases or fumes.

Up to one hundred maintenance workers will be exposed to the ink or the notified chemical. However, they are adequate trained, and wear disposable gloves to minimise the skin exposure. In addition, spillage is unlikely because of the fully-enclosed ink cartridges, however, personnel involved in cleaning-up of spills should protect themselves against respiratory, skin and eye exposure. Taking all into consideration, a occupational health risk is not expected for this category of workers.

In commercial printing, printing operators will be potentially exposed to the notified chemical when involved in replacement of inkjet drums. However, with the use of appropriate personal protective equipment and industrial standard work-wear, and the implementation of safe work

practices in the industrial site, these operators would not experience a significant health risk.

9.2.4.2 PUBLIC HEALTH

The notified chemical is a slight skin and severe eye irritant but is otherwise of low acute toxicity. It constitutes less than 5% of the finished product, Scitex 3600 Black Ink. Although dermal and ocular exposure may occur when changing inkjet cartridges, this would be unlikely given the packaging and ease of installation procedure. Consequently, the risk posed by the notified chemical is likely to be minimal.

Dermal exposure with the notified chemical will also occur during handling printed materials. However, once printed, the ink becomes bound to the surface, and therefore the health risk of public contact with the printed materials is determined to negligible.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Environment

Based on the available information, the overall environmental hazard of the notified chemical is expected to be low.

10.2. Health hazard

Based on the available data the notified chemical is classified as hazardous according the *NOHSC Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999). The classification and labelling details are: R22 – Harmful if swallowed and R41 – Risk of serious damage to eyes.

10.3. Human health

10.3.1. Human health – Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Human health – public

There is No Significant Concern to public health when used in the proposed manner.

11. RECOMMENDATIONS

REGULATORY CONTROLS

- The NOHSC Chemicals Standards Sub-committee should consider the following hazard classification for the notified chemical:
  - R22 – Harmful if swallowed; and
  - R41 – Risk of serious damage to eyes.

- Use the following risk phrases for products/mixtures containing the notified chemical at:
  - ≥25%: R22 – Harmful if swallowed;
  - ≥10%: R41 – Risk of serious damage to eyes;
  - 5%-10%: R36 – Irritating to eyes.

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure to the notified chemical during handling of the ink products:
  - Adequate induction and training programs for printer service personnel and operators at the commercial printing site.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical during handling of the ink products:
  - Wearing cotton or disposable gloves when servicing printers.
  - Wearing safety glasses, plastic or rubber gloves and industrial work-wear with rubber aprons when operating commercial printing equipment.

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

- Inkjet printers should be positioned in well-ventilated areas.

- 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.

Disposal

- The notified chemical should be disposed of in landfill.

Emergency procedures

- Spills/release of the notified chemical should be contained as described in the MSDS (i.e. contained with absorbent material and transfer to a sealable waste containers) and the resulting waste should be disposed of in landfill. Spillages should be prevented from entering drains, water sources or sewers.

- Personnel involved in clean-up of spillage should protect themselves against respiratory, skin and eye exposure.

11.1. 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(1) of the Act; if
  - the circumstances of use of the notified chemical have changed such that aquatic exposure is experienced, eg use as a textile dye, the notifier must provide all available test reports in full with adequate English translation.

and

(2) 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.

12. MATERIAL SAFETY DATA SHEET

12.1. Material safety data sheet

The MSDS for the notified chemical and the Scitex 3600 Black Ink product (containing <5% notified chemical) were provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSCA, 1994). They are published here as a matter of public record. The accuracy of the information on the MSDS remains the

responsibility of the applicant.

12.2. Label

The label for the Scitex 3600 Black Ink product (containing <5% notified chemical) provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

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