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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

C I DIRECT BLACK 195

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 Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Health and Family Services

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

C I DIRECT BLACK 195

1. APPLICANT

Epson Australia Pty Ltd of 70 Gibbes St CHATSWOOD NSW 2067 has submitted a standard notification statement in support of their application for an assessment certificate for C I Direct Black 195.

2. IDENTITY OF THE CHEMICAL

C I Direct Black 195 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical name, CAS number, molecular and structural formulae have been exempted from publication in the Full Public Report and the Summary Report.

The notified chemical contains no hazardous impurities at levels necessary to classify it as as a hazardous substance (11). Therefore, information on the purity of the chemical has been exempted from publication in the Full Public Report and the Summary Report.

Other names:	Substance H112287 C I Direct Black 195
Trade name:	Pro-jet Fast Black 2 Pro-jet Fast Black 2 Liquid (formulation)
Molecular weight:	619
Method of detection and determination:	HPLC separation using a gradient solvent system (acetonitrile and distilled water containing 1.0% w/v ammonium acetate) with detection at 570 nm

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	dark brown powder
Melting Point:	> 300°C
Density:	1450 kg/m^3
Vapour Pressure:	1.3 x 10^{-6} kPa (20-50°C)
Water Solubility:	> 27 g/L at 23°C
Surface Tension (of aqueous solution):	70.8 mN/m at 23°C

Fat Solubility:	< 0.11 mg/100 g standard fat HB 307 at 37°C
Partition Co-efficient (n-octanol/water) log P_{ow}:	- 1.6 at 25°C
Hydrolysis as a function of pH:	10% hydrolysis after 120 h at pH 4, 7 or 9
Adsorption/Desorption:	not determined
Dissociation Constant pKa**:**	not determined
Flash Point:	not applicable
Flammability Limits:	does not propagate combustion
Autoignition Temperature:	363°C
Explosive Properties:	not explosive
Reactivity/Stability:	non-oxidising

Comments on the physico-chemical properties

Tests were performed according to EEC test guidelines and at facilities complying with OECD principles of Good Laboratory Practice.

Adsorption/desorption : The notifier's comments indicate strong adsorption of the notified chemical may occur. However, the relatively high solubility, low partition coefficient, and low fat solubility of the notified chemical would tend to indicate low adsorption. Furthermore, during normal use a proportion of the notified chemical will encounter sewage and recycling effluents, the alkaline nature of these systems is likely to result in low sorption of the notified chemical to solids.

By EEC definition, a chemical has surface activity when the surface tension is less than 60 mN/m, thus the notified chemical is not considered surface active (EEC Directive 92/69, A5 'Surface Tension' (1992).

4. PURITY OF THE CHEMICAL

Degree of purity:	92.1% (range 85-95%)
Impurities:	ammonia (4.4%), water (6.6%) and inorganics (1.3%) and an impurity similar in structure to the notified chemical at 1.1%
Additives/Adjuvants:	none

5. USE, VOLUME AND FORMULATION

The notified chemical will be used as a component of an aqueous black ink preparation used in ink-jet reprographic processes. It is to be imported as a 3-4%

aqueous solution in a sealed cartridge at a rate of 1 tonne for the first year and 1-3 tonnes per year for the following 4 years.

6. OCCUPATIONAL EXPOSURE

The voulme of ink in a cartridge will vary depending on the design of the printer - the range is 2-50 ml of the ink formulation. All printer designs enable the replacement of the black cartridge separately. Normal handling, involving replacement of the spent ink cartridge by service technicians or office workers will not result in exposure to the ink and such exposure should only result if the cartridge is faulty and ruptures. Under normal conditions of use, several milligrams of notified substance are expected on each printed page.

7. PUBLIC EXPOSURE

Normal handling involving replacement of spent ink cartridge by consumers is not expected to result in significant exposure to the notified chemical. However, exposure may occur through accidental rupture of a cartridge.

The public may come in contact with paper printed with the formulated ink, but the potential for public exposure is expected to be minimal. This is because the printed paper will contain only milligram quantities of the notified chemical per sheet and the notified chemical being insoluble on contact with the surface of paper.

Negligible public exposure is expected as a result of disposal of empty cartridges or printed paper or recycling of printed paper.

8. ENVIRONMENTAL EXPOSURE

. Release

During normal use the notified substance will become bound to cellulosic substrates and in this state is not expected to adversely impact on the environment. Although the notified chemical is soluble at the pH of the ink solution (pH 9), it becomes insoluble on contact with paper, a result of the lower pH of the paper.

Environmental exposure will result from the disposal of printed paper and discarded cartridges. In addition to landfill, printed paper may also be recycled after first being subjected to a de-inking process. De-inking wastes are expected to go to trade waste sewers. On combustion oxides of carbon, nitrogen and sulphur will be released.

. Fate

The relatively high water solubility of the notified chemical indicates that unbound residues released directly to the aquatic compartment are likely to remain in solution (particularly in alkaline sewers) where they will be rapidly diluted.

Results from biochemical oxygen demand tests (BOD_5 < 0.1 g/L, COD 1.29 g O_2/g) indicate that significant biodegradation is unlikely under aerobic conditions. In a modification of the Zahn-Wellens test (OECD TG 302B) colorimetric analysis showed a 52% mean colour reduction over 28 days, indicating significant bioelimination has occurred.

The bioaccumulation potential of the notified chemical was not investigated. The low partition coefficient (log P_{OW} = -1.6), low fat solubility (<1.1 mg/kg) and the relatively high water solubility (2.70 % w/w) of the notified chemical indicate that significant bioaccumulation is not likely.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of C I Direct Black 195

Test	*Species*	*Outcome*	*Reference*
Acute oral toxicity	Rat	LD_{50} > 2000 mg/kg	(1)
Acute dermal toxicity	Rat	LD_{50} > 2000 mg/kg	(3)
Skin Irritation	Rabbit	slight irritant	(4)
Eye irritation	Rabbit	moderate irritant	(6)
Skin sensitisation	Guinea pig	sensitiser	(8)

9.1.1 Oral Toxicity (1)

LD_{50}: > 2000 mg/kg

Species/strain: Wistar-derived albino rats (Alp K:APF SD)

Number/sex of animals: 5 males, 5 females

Observation period: 14 days

Method of administration: gavage (vehicle - de-ionised water)

Clinical observations: no significant signs of toxicity

Mortality: no deaths

Morphological findings: no macroscopic abnormalities detected at necropsy

Test Method: directive 84/449/EEC (2) Test B1

Result: low toxicity via the oral route, no significant signs of toxicity to rats

9.1.2 Dermal Toxicity (3)

LD_{50}:: > 2000 mg/kg

Species/strain: Wistar-derived albino rats (Alp K:APF SD)

Number/sex of animals: 5 males, 5 females

Observation period: 14 days

Method of administration: as a paste with de-ionised water

Clinical observations: no significant signs of toxicity; slight skin irritation overall

Mortality: no deaths

Morphological findings: no macroscopic abnormalities detected at necropsy

Test Method: directive 84/449/EEC (2) Test B3

Result: low toxicity via the dermal route, no significant signs of toxicity to rats

9.1.3 Skin Irritation (4)

Species/strain: New Zealand White rabbits

Number/sex of animals: 3 males

Method of administration: sample moistened with de-ionised water applied under occlusive gauze dressing for four hours.

Test Method: directive 84/449/EEC (2) Test B4

Draize Scores[i] (5):

	Time after decontamination									
	30-60 min		***1 day***		***2 days***		***3 days***		***7 days***	
Animal	***e[a]***	***o[b]***	***e[a]***	***o[b]***	***e[a]***	***o[b]***	***e[a]***	***o[b]***	***e[a]***	***o[b]***
1	2	2	1	1	0	0	0	0	0	0
2	2	4	1	3	0	2	0	0	1	0
3	1	1	0	1	0	0	0	0	0	0

[i] See Attachment 1 for Draize Scales
[a] Erythema [b] Oedema

Result: slight irritant to rabbit skin

9.1.4 Eye Irritation (6)

Species/strain: **N**ew Zealand White rabbits

Number of animals: 3 females

Method of administration: test substance (100 mg) instilled in conjunctival sac of one eye

Draize Scores[i] (5):

	Time after instillation									
Animal	***1 day***		***2 days***		***3 days***		***4 days***		***7 days***	
Cornea	***o[a]***	***a[b]***	***o[a]***	***a[b]***	***o[a]***	***a[b]***	***o[a]***	***a[b]***	***o[a]***	***a[b]***
1	3	1	2	2	2	2	1	1	1	1
2	1	2	1	2	1	2	1	1	1	1
3	1	1	1	1	1	1	1	1	1	1
Iris										
1	1		1		0		0		0	
2	0		0		0		0		0	
3	1		0		0		0		0	
Conjunctiva	***r[c]***	***c[d]***	***d[e]***	***r[c]***	***c[d]***	***d[e]***	***r[c]***	***c[d]***	***d[e]***	***r[c]***	***c[d]***	***d[e]***	***r[c]***	***c[d]***	***d[e]***
1	2	2	1	2	1	0	2	0	0	2	0	0	0	0	0
2	2	2	1	2	1	0	2	1	0	1	0	0	0	0	0
3	2	2	1	2	1	0	1	1	0	1	0	0	0	0	0

[i] See Attachment 1 for Draize Scales
[a] Opacity [b] Area [c] Redness [d] Chemosis [e] Discharge

Test Method: directive 84/449/EEC (2) Test B5

Result: moderate irritant to the rabbit eye

9.1.5 Skin Sensitisation (7)

Species/strain: albino male guinea pigs/ AlpK:Dunkin Hartley

Number of animals: 20 test group, 10 control group

Induction procedure: injections of 1% (w/v) in de-ionised water and 1% (w/v) in FCA plus de-ionised water (1:1); on day 8 a 48 h topical application of 30% (w/v) in de-ionised water

Challenge procedure: on day 22 topical application of test substance in de-ionised water under occlusive dressing

Challenge outcome:

Challenge concentration	***Test animals***		***Control animals***	
	24 hrs*	***48 hrs****	***24 hrs***	***48 hrs***
3%	0/20**	0/20	0/10	0/10
10%	5/20	0/20	1/10	0/10

* Time after patch removal
** Number of animals exhibiting positive response

Test Method: directive 84/449/EEC (2) Test B6

Result: weak sensitiser

9.2 Repeated Dose Toxicity (8)

Species/strain: rat/ AlpK: APfSD (Wistar derived)

Number/sex: 6 males and females

Method of administration: orally by gavage (de-ionised water)

Dose: 0, 50, 200 or 1000 mg/kg/day

Duration of administration: 28 days plus 14 day recovery for 0 and 1000 mg/kg/day

Toxicologically Significant Observations:

1. Clinical

clinical signs of toxicity in 1 male of the high dose group; two males and females in the high dose group died of causes unrelated to administration of the notified chemical

2. Clinical Chemistry/Haematology

one male in the high dose group exhibited slight anaemia

3. Necropsy Findings/ Histopathology

the kidneys were identified as the target organ; tubular degeneration was observed in all rats in the 200 and 1000 mg/kg/day dose groups; the severity of the lesions was similar in both sexes but less severe at the lower dose level; tubular degeneration was correlated with changes in kidney function in severely affected rats manifested as proteinuria and increases in absolute kidney weight and kidney to bodyweight ratio; tubular degeneration was not resolved during the recovery period but the other changes were resolved.

Test Method: directive 84/449/EEC (2) Test

Result: the kidney was identified as the target organ, however, no significant signs of toxicity were observed and clinical chemistry and haemotology parameters were unaffected

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (9)

Strains: *Salmonella typhimurium* TA 1537, TA 1538, TA 98, TA 100 and *Escherichia coli* WP2*uvrA* (pKM101)

Concentration range: 8.0 to 6250 μg/ plate

Test Method:	directive 84/449/EEC (2) Test B4
Result:	no significant dose-related induction of mutations above background in the presence or absence of metabolic activation provided by rat liver S9

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (10)

Species/strain:	mouse/ C57BL/ 6J fCD-1/AlpK
Number and sex:	5 males and females
Doses:	1460 and 2330 mg/kg (females) 3130 and 5000 mg/kg (males)
Method of administration:	gavage (vehicle - corn oil)
Test Method:	directive 84/449/EEC (2) Test B12
Result:	no significant increases in the incidence of micronucleated polychromatic erythrocytes over vehicle control values were observed at either dose level in either sex at any of the sampling times investigated

9.4 Overall Assessment of Toxicological Data

C I Direct Black 195 was of low toxicity via the oral and dermal routes in the rat with both LD_{50}s > 2000 mg/kg. It was a moderate irritant to the eye and a slight irritant to the skin of the rabbit. It was a weak skin sensitiser in guinea pigs. When rats were treated orally with up to 1000 mg/kg/day for 28 days, irreversible tubular degeneration of the kidney was observed in the 200 and 1000 mg/kg/day dose groups. However, there were no treatment-related effects at the lowest dose level of 50 mg/kg/day. C I Direct Black 195 was found to be non-mutagenic *in vitro* to *Salmonella typhimurium* TA 1537, TA 1538, TA 98 and TA 100 and to *Escherichia coli* WP2*uvrA* (pKM101) and non-clastogenic *in vivo* in bone marrow cells of the mouse.

On the basis of the submitted data, the notified chemical would not be classified as hazardous in accordance with Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (11) in relation to acute lethal effects (oral, dermal); irritant effects (skin, eye); sensitising effects (skin), mutagenic effects or severe effects after repeated or prolonged exposure (oral route).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The table below summarises the ecotoxicity tests provided by the notifier for C I Direct Black 195. These tests were performed in accordance with OECD guidelines and principles of GLP.

Ecotoxicity test results (nominal concentrations)

Species	***Test***	***Result***
Rainbow Trout, *Oncorhynchus mykiss*	96 hour acute EEC Directive 84/449/EEC Test C1	LC_{50} = >100 mg/L
Daphnia, *Daphnia magna*	48 hour immobilisation EEC Directive 84/449/EEC Test C2	EC_{50} > 100 mg/L
Activated sludge	ETAD Method 103 (aerobic)	19% inhibition of respiration in 100 mg/L

Results are reported in terms of nominal concentrations as the mean measured concentrations were found to be within 97% of the nominal value. No mortalities were reported in either aquatic study. In the fish study, the intense colour of the test solutions prevented observations of toxicity symptoms. Similar observations were not noted in the *Daphnia* report. These results show that the notified chemical is practically non-toxic to the fish and daphnia species studied.

Algal growth inhibition testing was not performed on the basis of the low toxicity shown by the other aquatic studies. Testing of similar chemicals submitted by the same notifier have shown slight algistatic effects. However, these results may be attributed to the colouration of the test solution and the resultant reduction in light transmittance as opposed to any inherent chemical toxicity.

The potential effects of the active on sewage treatment were investigated under aerobic and anaerobic conditions. Under aerobic conditions a 100 mg/L (nominal) of the notified substance in activated sludge caused a 19% inhibition in the respiration rate of the microorganisms (ETAD Method 103). While this may indicate slight inhibition, significant effects on sewage treatment systems are considered unlikely as the actual concentration will be significantly lower. The active had no effect on nitrification (Department of the Environment, UK 1980. The Assessment of the Nitrifying Ability of Activated Sludge (Tentative Methods). HMSO London). Under anaerobic conditions, concentrations of up to 1.5% w/w of the active were reported to have had no significant effects on the levels of gas production. Colorimetric studies indicated a mean colour removal of 88% at the conclusion of digestion experiments.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

C I Direct Black 195 is not expected to present a hazard to the environment. During normal use the chemical will be bound to the treated substrate. Recycling of treated paper could result in the release of a proportion of the notified chemical to the aquatic compartment where it will be rapidly diluted to environmentally negligible levels. Where recycling does not occur, the notified chemical will be widely distributed in landfills around Australia where the notified chemical is expected to remain bound to the treated paper. In the event of leaching the environmental effects are expected to be negligible due to the low toxicity and low bioaccumulation potential of the notified chemical.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The toxicological profile of C I Direct Black 195 suggests that it is unlikely to be acutely toxic via the oral and dermal routes and is likely to be neither mutagenic nor clastogenic. However, it is expected to be moderately irritating to the eye, slightly irritating to the skin and a weak skin sensitiser. It is unlikely to exhibit toxic effects on repeated or prolonged exposure. C I Direct Black 195 is not classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (11) in relation to the toxicological data provided.

The notified chemical is to be used in ink-jet reprographic processes and is to be imported in sealed ink-jet cartridges which are inserted directly into ink-jet printers. Therefore, exposure to the notified chemical during normal handling is not expected other than in the unlikely event that the cartridge is faulty and ruptures.

The occupational health risk associated with importation, storage, use or disposal of the notified chemical is expected to be minimal.

The potential for public exposure to the notified chemical by handling the ink cartridges is expected to be negligible. Exposure by contact with the printed paper is also expected to be negligible because of the low level of the notified chemical used in the ink and its insolubility on the surface of paper.

13. RECOMMENDATIONS

To minimise occupational exposure to C I Direct Black 195 the following guidelines and precautions should be observed:

- in the event of a spill or during routine cleaning or maintenance, if engineering controls or work practices are insufficient to reduce exposure of C I Direct Black 195 to a safe level, personal protective devices which conform to and are used in accordance with Australian Standards (AS) or Australian/ New Zealand Standards (AS/NZS) for eye protection (AS 1336, AS/NZS 1337) (12,13), impermeable gloves (AS 2161) (14) and overalls (AS 2919) (16) should be worn; and

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

14. MATERIAL SAFETY DATA SHEET

The MSDS for the ink containing the notified chemical was provided in accordance with Worksafe Australia's *National Code of Practice for the Preparation of Material Safety Data Sheets* (16).

This MSDS was provided by the applicant as part of their notification statement. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of C I Direct Black 195 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

1. ICI Project AR5204, January 1991. *Acute Oral Toxicity Study with H112287 in Rats*. ICI Toxicology Laboratory, Cheshire, United Kingdom.

2. EEC Council Directive 84/449 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations, *Official Journal of the European Communities,* No. L251 (19 September 1984).

3. ICI Project CR2752, June 1990. *Acute Dermal Toxicity Study with H112287 in Rats.* ICI Toxicology Laboratory, Cheshire, United Kingdom.

4. ICI Project EB3791, June 1990. Primary Skin Irritation Study with H112287 in Rabbits. ICI Toxicology Laboratory, Cheshire, United Kingdom.

5. 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**.

6. ICI Project FB3791, June 1990. *Primary Eye Irritation Study with H112287 in Rabbits*. ICI Toxicology Laboratory, Cheshire, United Kingdom.

7. ICI Projects GG4944 and GG4763 July 1990. *Contact Hypersensitivity to H112287 in Albino Guinea Pigs, Maximisation Test*, ICI Toxicology Laboratory, Cheshire, United Kingdom.

8. ICI Project KR1116, June 1990. *Subacute 28-Day Oral Toxicity Gavage Study with H112287 in Rats*. ICI Toxicology Laboratory, Cheshire, United Kingdom.

9. ICI Projects YV2738, YV2739 and YV2763, June 1990. *Salmonella typhimurium and Escherichia coli Reverse Mutation Assay for Azo dyes* w*ith H112287*. ICI Toxicology Laboratory, Cheshire, United Kingdom.

10. ICI Project SM0441, June 1990. *Micronucleus Assay in the Bone Marrow Cells of the Mouse*. ICI Toxicology Laboratory, Cheshire, United Kingdom.

11. National Occupational Health and Safety Commission 1994, *Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]*, Australia Government Publishing Service, Canberra, Australia.

12. Standards Australia, 1994, *Australian Standard 1336-1994, Recommended Practices for Eye Protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney, Australia.

13. Standards Australia, Standards New Zealand 1992, *Australian/ New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney, Australia, Standards Association of New Zealand Publ. Wellington, New Zealand.

14. Standards Australia 1978, *Australian Standard 2161-1978, Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves*), Standards Association of Australia Publ., Sydney, Australia.

15. Standards Australia, 1987, *Australian Standard 2919 - 1987 Industrial Clothing,* Standards Association of Australia Publ., Sydney, Australia.

16. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]*, AGPS, Canberra, Australia.

Attachment 1

The Draize Scale 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 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