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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

SANDODERM BLACK R

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Director
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FULL PUBLIC REPORT**SANDODERM BLACK R****1. APPLICANT**

Clariant Australia Pty Ltd of 675 Warrigal Road Chadstone Victoria 3148 has provided a standard notification statement for an assessment certificate for Sandoderm Black R.

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided the notified chemical is considered to be non-hazardous. Therefore, the chemical name, CAS number, molecular and structural formula, composition, spectral data and main impurities are been exempted from publication in the Full Public Report and the Summary Report.

Trade name: Sandoderm Black R

Molecular weight: 1299

3. PHYSICAL AND CHEMICAL PROPERTIES

Sandoderm Black R is a complex product of one reaction between two different monazole dyestuffs and a chromium 3 salt. The following data refers to the notified chemical and not to the product (Sandoderm Black R Liquid).

Appearance at 20°C and 101.3 kPa:	black powder
Odour:	unknown
Melting Point:	> 270°C
Density:	1695 kg/m ³
Vapour Pressure:	not provided. The high melting point and high molecular weight of the chemical indicates vapour pressure will be negligible.
Water Solubility:	96.2 g/L at 20°C
Fat Solubility:	0.17±0.05 mg/100gm at 37°C
Partition Co-efficient (n-octanol/water) log P_{ow}:	< -3.4
Hydrolysis as a function of pH:	not provided
Adsorption/Desorption:	not provided; the dye is expected to have low affinity to soil.
Dissociation Constant	

pKa:	not provided
Surface Tension:	44.7 mN/m at 20°C
Flammability Limits:	not provided
Combustion Products:	not provided
Pyrolysis Products:	not provided
Decomposition Temperature:	not provided
Decomposition Products:	not provided
Autoignition Temperature:	relative self-ignition temperature 385°C
Explosive Properties:	not explosive
Reactivity/Stability:	the notifier has stated that the product will not react exothermically with flammable material
Particle size distribution:	< 10 µm (4.5% of the notified chemical)

• **Comments on physico-chemical properties**

The dye is the sodium salt of a sulphonic acid. It has good water solubility and it can be assumed that the molecule is dissociated close to 100% in the pH range of 4 - 9.

Hydrolysis has not been observed during the application process in which the dyestuff was involved. The dye contains a number of amide moieties that have the potential to hydrolyse but are unlikely to do so under environmental conditions.

The surface tension value indicates the dye is surface active and has the potential to adsorb to soil/sediment, in spite of high water solubility.

4. PURITY OF THE CHEMICAL

Degree of purity : 29%

Hazardous impurities:

Nature of Impurity	CAS No	Mean (%)	Production range (%)	Health Effects
sodium chloride	7647-14-5	17	1	LD ₅₀ (oral, rat):3000 mg/kg; causes mild irritation to the skin and eye of rabbit (18)
acetoacetic acid anilide	102-01-2	1	0.5-2	LD ₅₀ (oral, rat):5400 mg/kg; by intraperitoneal route; weak allergen(18)

Other impurities:

Nature of Impurity	CAS No	Mean (%)	Production range (%)
K ⁺ , NH ₄ ⁺ , SO ₄ ²⁻ -CH ₃ COO ⁻	-	1	0.5-2
water	7732-18-5	2	1-6
main impurities			50%

Additives/Adjuvants: none

5. INDUSTRIAL USE

The notified chemical, Sandoderm Black R, will be imported into Australia as a 30% component in an aqueous solution (Sandoderm Black R Liquid). The notifier estimates that 1-10 tonnes of the chemical will be imported annually for the next five years as Sandoderm Black R Liquid.

The notified chemical is an acid dye which will be used for dyeing leather used ultimately for furniture manufacture. The notified chemical may be used by itself, but in most cases it will be used in combination with other dyes.

Two tanneries are expected to use the dye and both are located in metropolitan areas.

6. OCCUPATIONAL EXPOSURE

Sandoderm Black R Liquid will be imported in plastic drums and delivered to Clariant warehouse. The drums are then delivered to Clariant customers. No decanting is carried out at the warehouse.

The notifier expects two tanneries to use Sandoderm Black R Liquid and at each tannery 3 operators will be exposed to the notified chemical.

During wet processing, leather is coloured using dye in a revolving drum. Sandoderm Black R Liquid may be used by itself, but in most cases it will be used in combination with other dyes.

The liquid dye is weighed and added to a covered vessel fitted with a stirrer, and dissolved in water. The dye solution is pumped into the revolving drum containing the wet leather.

The notifier estimates that the time spent in handling the product containing the notified chemical in these operations as 1 hour per operator per week.

Operators handling the notified chemical will be required to wear personal protection.

7. PUBLIC EXPOSURE

The notifier estimates that 95-98% of the dye solution will be taken up by the leather. It is further claimed that the dye will be chemically bound to the substrate. The dyed leather will be resin coated on the surfaces to be in contact with the public.

The public will come into contact with leather articles which have been coloured using dyes containing the notified chemical. If the notified chemical is not 100% bound to the article, small amounts of the chemical may be released from the leather resulting in dermal, and possibly ocular, contact. However, as the dyed leather is resin coated in contact areas, and the notifier claims that the dye is bound to the leather articles, significant public exposure to the notified chemical is unlikely.

Minor public exposure may result from accidental spillage during transport and storage of the dye.

8. ENVIRONMENTAL EXPOSURE

Release

Observation during trials with the dye indicate that 95-98% of dye is uptaken by the leather. Manufacturer's details show the dye has an affinity number of 99 for high affinity leather. The affinity number expresses the percentage of applied dyestuff which is bound to the substrate in the first half of a defined dyeing process. The notified dye will be used mainly for high-affinity leather.

Waste process water containing the dye goes to treatment plants on site, and effluent to the sewer is subject to water authority regulations.

Fate

The bulk (95-98% fixation) of the dye will become chemically bound to the leather and in this state is not expected to impact on the environment. Some minor losses to the environment might occur through spills at the warehouse, during transit, or at the tannery. The major route for environmental release has been identified as unfixed dye which has been washed from the treated leather.

These unfixed residues (2-5%) will enter the aquatic environment after discharge from the tannery and subsequent treatment at sewage treatment plants. The exact fate of the dye residues is unclear, due to uncertainties relating to the degree of sorption onto sediments.

After entering the sewage works, unfixed residues may be removed through degradation (chemical or biological) or sorption to sludge. In view of the high water solubility, it is likely that significant quantities of the dye will remain in the aquatic compartment. However, the dye's surface activity will increase its adsorption potential; any dye partitioned to the sediment will be removed with the sludge during treatment at the dyehouse and sewage works. While azo dyes are generally stable under aerobic conditions, they are susceptible to reductive degradation under the anaerobic conditions characteristic of sediment [1].

- Biodegradation

The dye was tested for its ready biodegradability in accordance with OECD Guideline 301E (modified OECD screening test). The biodegradation of the test article was followed by exposing it to microorganisms from the secondary effluent of

a domestic waste water sewage plant and measuring the dissolved organic carbon (DOC) content. The notified chemical appeared to be not readily biodegradable within 28 days as the DOC content remained unchanged.

The inherent biodegradability of the dye was tested according to OECD TG 302B (Modified Zahn-Wellens Test). The dye was degraded under the test conditions by 12% within 28 days. The result indicates that the dye has the potential for biodegradation and is unlikely to persist indefinitely in the environment.

- Bioaccumulation

The dye is unlikely to bioaccumulate due to its high water solubility (96.2 g/L) and low log Pow (< -3.4) and fat solubility (0.17 mg/100 g) . Also, the dye's large molecular size is likely to inhibit membrane permeability and prevent uptake during exposure [2,3].

9. EVALUATION OF TOXICOLOGICAL DATA

The toxicological data submitted relates to Sandoderm Black R which includes impurities.

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Sandoderm Black R

Test	Species	Outcome	Reference
acute oral toxicity	rat	LD ₅₀ > 5000 mg/kg	(4)
acute dermal toxicity	rat	LD ₅₀ > 2000 mg/kg	(5)
skin Irritation	rabbit	non-irritant	(6)
eye irritation	rabbit	slight irritant	(7)
skin sensitisation	guinea pig	non-sensitiser	(8)

9.1.1 Oral Toxicity (4)

Groups of outbred Wistar rats (5 per sex; approximately 9-11 weeks old) were administered a single gavage dose of 2000 (LD) or 5000 (HD) mg of Sandoderm Black R in polyethylene glycol/kg. The animals were maintained for 15 days. Mortality, and clinical signs of toxicity, were assessed 4 times during day 1, and daily thereafter. Body weight was determined on days 1 (pre-dosing), 8 and 15. An autopsy was performed on all animals which prematurely died, or at the completion of the study.

Two HD females were found dead 24 hours after chemical administration. Slight lethargy, dyspnoea, hunched posture and ruffled fur were features of LD males and females during the initial 2-6 days of the study. In addition, ataxia and diarrhoea were occasionally seen during the initial days of the study in HD males and females. No pathological abnormalities were found at autopsy.

The acute oral LD₅₀ of the notified chemical was greater than 5000 mg/kg in male and female rats.

9.1.2 Dermal Toxicity (5)

A dose of 2000 mg/kg of Sandoderm Black R in polyethylene glycol was applied to shaved, intact skin of outbred Wistar rats (5 per sex, approximately 10-11 weeks old). The area was occluded for 24 hours, after which the residual chemical was removed using a water moistened tissue. The study was terminated after 15 days. Mortality and clinical signs of toxicity were assessed 4 times during test day 1, and daily thereafter. Body weight was determined on days 1 (pre-dosing), 8 and 15. An autopsy was performed on all animals at the completion of the study.

No deaths were recorded, no toxicologically related lesions were seen on autopsy, and no evidence of skin irritation were noted during the study. Reduced body weight gain was noted amongst 4 of 5 males, and 1 of 5 females during the first week of the study.

The acute dermal LD₅₀ of the notified chemical was greater than 2000 mg/kg in male and female rats.

9.1.3 Skin Irritation (6)

The fur was removed from the back of 3 New Zealand White rabbits (2 males, 1 female; 14-15 weeks old), and 500 mg of Sandoderm Black R was applied to the intact skin for 4 hours. Residual chemical was then removed. The study was terminated after 72 hours. Animals were examined daily for clinical signs of toxicity. Body weight was determined on the day of chemical application, and at study termination. Skin reactions were assessed 1, 24, 48 and 72 hours after chemical removal. The severity of the reactions were determined by the degree of erythema, eschar formation and oedema.

No deaths, skin or clinical abnormalities were noted during the study. The notified chemical did not cause dermal irritation in rabbits.

9.1.4 Eye Irritation (7)

<i>Species/strain:</i>	New Zealand White rabbits
<i>Number of animals:</i>	two males and one female
<i>Method of administration:</i>	100 mg of the notified chemical applied into the conjunctival sac of the left eye. Eyes were washed 2 days after chemical instillation.
<i>Test Method:</i>	directive 84/449/EEC (2) Test B1
<i>Result:</i>	Slight irritant

Draize (5) Scoresⁱ

Animal	Time after instillation											
	1 day			2 days			3 days			7 days		
CORNEA:	opacity area			opacity area			opacity area			opacity area		
1	1			1			1			1		
2	1			1			1			0		
3*	1			1			1			1		
IRIS												
1	0			0			0			0		
2	0			0			0			0		
3*	0			0			0			0		
CONJUNCTIVA	r ^a	c ^b	d ^c	r ^a	c ^b	d ^c	r ^a	c ^b	d ^c	r ^a	c ^b	d ^c
1	1	1		1	1		1	0		0	0	
2	1	2		2	1		2	1		0	0	
3*	0	2		0	1		0	0		0	0	

^a redness ^b chemosis ^c discharge

9.1.5 Skin Sensitisation (8)

Thirty Dunkin-Hartley albino guinea pigs were divided into a control (5 per sex) and a treatment group (10 per sex). The hair was removed, using clippers, from the scapular region of each animal. Induction doses consisted of a series of intradermal injections given either side of the clipped area. The intradermal injections were either the test substance dissolved to 1% (w/w) with saline, 50:50 Freund's Complete Adjuvant with saline, or 1% test substance in 50:50 Freund's Complete Adjuvant and saline. One week after the injections, 25% of the test compound in saline, was applied to skin over the injection sites of the test animals, and covered with an occlusive dressing. The dressing was removed after 48 hours. Control animals were treated as described, with the omission of the test material. Control and treatment groups were challenged 2 weeks after the epidermal induction dose. Hair was removed from the right and left flanks of each guinea pig. Twenty five percent of the test compound in saline, was applied to the left flank, and saline was applied to the right flank, and covered with an occlusive dressing for 24 hours. Application sites were assessed for erythema and oedema following removal of the dressing. A second challenge dose was applied 2 weeks after the first. The control animals were treated with the vehicle (saline) alone. The application sites were assessed for redness and swelling immediately, 24 and 48 hours after removal of the test material. In addition, animals were examined for clinical signs of toxicity and mortality on a daily basis, and body weights were determined at the beginning and end of the study. An autopsy was carried out on each animal at the conclusion of the study.

One of 10 males showed a positive dermal reaction (erythema, grade 1) 24 hours after the first challenge, and 1 of 10 females showed erythema (grade 1) 24 hours, and 48 hours (grade 2) after the second challenge.

The notified chemical did not cause skin sensitisation in the guinea pig.

9.2 Repeated Dose Toxicity (9)

Groups of 5 Wistar rats per sex (approximately 8 weeks old) were administered 0, 50 mg (LD), 200 mg (MD) or 1000 mg (HD) of Sandoderm Black R (in 4% carboxymethyl cellulose)/kg/day, by gavage, for 28 days. Clinical signs of toxicity and animal viability were assessed daily, food consumption and body weight was

determined weekly, and an ophthalmic examination was carried out during study week 4. Blood was collected for haematology and clinical biochemistry, and urine collected for urinalysis, at the completion of the study. Autopsies, which included selected organ histology, and weight determination, were carried out at study termination.

A decrease in RBC count, haemoglobin concentration and haematocrit were noted in HD females at the conclusion of the study. Relative kidney weight was increased in females at the LD and MD, but not at the HD. Pathology was unaffected. The increased organ weight is of questionable toxicological significance due to the lack of a dose response.

9.3 Genotoxicity

9.3.1 *Salmonella Typhimurium* Reverse Mutation Assay with Sandoderm Schwarz R (HH 1050) (10)

<i>Species/strain:</i>	<i>Salmonella typhimurium</i> TA 1535, TA 1537, TA 98, TA 100
<i>Concentration range:</i>	The assay was performed in two independent experiments, using identical procedures, both with and without liver microsomal activation. 10, 100, 333.3, 1000 and 5000 µg/plate
<i>Metabolic activation:</i>	rat liver S9
<i>Test Method:</i>	directive 84/449/EEC (5) Test B14
<i>Result:</i>	during the mutagenicity test and under experimental conditions reported, the test article did not induce point mutations by base pair changes or frameshifts in the genome of the strains used. Sandoderm Schwarz R (HH 1050) is considered to be non-mutagenic in this <i>Salmonella typhimurium</i> reverse mutation assay

9.3.2 Micronucleus Assay in Bone Marrow Cells of the Mouse with Sandoderm Schwarz R (HH 1050) (11)

<i>Dose levels:</i>	the test article was dissolved in distilled water; the solvent was used as negative control; the volume administered orally was 20 ml/kg b.w. 24h, 48h and 72h after a single application of the test article the bone marrow cells were collected for micronuclei analysis
<i>Comments:</i>	<p>in comparison with corresponding negative controls there was no substantial enhancement in the frequency of the detected micronuclei at the preparation interval after application of the test article</p> <p>an appropriate reference mutagen was induced as positive control which showed a distinct increase of induced micronucleus frequency</p>

Test Method: 84/449/EEC (5) Test B12

Result: the test material did not induce micronuclei as determined by the micronucleus test with bone marrow cells of the mouse

Summary of genotoxicity studies using Sandoderm Black R.

STUDY TYPE	TEST OBJECT	CONCENTRATION	RESULT	REF.
Reverse mutation	<i>S. typhimurium</i> strain TA98, TA100, TA 1535, TA1537	10-5000 mg/plate (\pm rat liver S9 fraction activation)	-ve	10
Micro-nucleus formation	Mouse erythrocytes	2000 mg/kg (5 males and females).	-ve	11

9.4 Overall Assessment of Toxicological Data

The studies demonstrated that the notified chemical (Sandoderm Black R) has low acute oral toxicity ($LD_{50} > 5000$ mg/kg in rats) and dermal toxicity ($LD_{50} > 2000$ mg/kg in rats), is a slight eye irritant, and does not cause dermal irritation or sensitisation. Twenty eight day repeat dose studies in rats indicated that the target organ is the kidney, although no histological or biochemical evidence of cellular damage was evident. The compound, was found to be non-mutagenic to *Salmonella typhimurium* and did not induce micronuclei as determined by the micronucleus test with bone marrow cells of the mouse.

On the basis of submitted data, the notified chemical would not be classified as hazardous in accordance with Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)] in relation to acute and dermal toxicity, repeated dose toxicity, sensitising effects (skin), irritant effects (skin and eye), non-mutagenicity in *Salmonella typhimurium* and from negative results in the micronucleus test with bone marrow cells of the mouse.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicological studies have been provided.

Test	Species	Result
Acute toxicity	Rainbow trout	96h LC50 = 11.1 mg/L NOEC > 2.5 mg.L ⁻¹
Acute toxicity	<i>Daphnia magna</i>	24h LC50 = 617 mg/L NOEC = 58 mg/L

The above studies were conducted according to OECD test guidelines. The results indicate the notified chemical is slightly to moderately toxic to fish and practically non-toxic to daphnids.

No algal toxicity studies were provided. The notifier claims to have no data on similar products and are not aware of any structure - activity relationship applicable to algae toxicity. The dye may have slight algistatic effects (i.e. growth inhibition) due to the dye solution reducing the quality or quantity of light transmitted to the algae.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

As indicated above, 95-98% of the dye is fixed in the dyeing process, thus 2-5% of the applied dye could be discharged into effluents at the tanneries where it is used. The notifier has calculated a worst-case environmental release concentration when the dye is used alone. A typical dyeing for 600 kg of leather involves 18 kg of dye of which 0.9 kg is lost to waste water (8400 L). As the concentration of the active dye in this process is 24%, the resulting concentration in the wash water is 25 ppm. Further dilution of 1:10 is likely to occur in the on-site waste water treatment plant. Therefore, dye lost to the sewerage system is estimated to be ~2.5 ppm for this dyeing process.

As the tanneries are located in metropolitan regions where the sewerage flow is greater than 100 ML/day, the dye lost to the sewer system will be further diluted to ppb levels. Further dilution will occur in the receiving waters in the order of 1:10, resulting in an estimated environmental concentration (EEC) for the dye of < 1 ppb. As the EEC is several orders of magnitude lower than the acute toxicity values for fish and aquatic invertebrates, it is unlikely that the dye will present a hazard to the environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical was not found to be a skin sensitiser. It is a non-irritant to the skin and is a slight eye irritant.

The notified chemical is imported as a 30% component in an aqueous solution. The most likely routes of exposure are splashes in the eye and on the skin. Although the chemical is a slight eye irritant, the effect is not sufficiently severe to require classification as a hazardous chemical according to *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(1994)] on the basis of eye irritation. However, proper industrial hygiene, which includes the use of eye protection in this case, should be applied when handling the chemical. Aerosol formation is possible during weighing and transferring processes. Also fine sprays of mist containing the notified chemical could be airborne during mixing. However, the level of risk will be minimal as the mixing processes are normally performed in sealed containers.

The applicant has stated that tannery operators will be using the notified chemical. All workers handling the notified chemical will wear chemical goggles or safety glasses and impermeable gloves during tanning operations. Material safety data sheet (MSDS) will be available on site and normal practice of good housekeeping will be applied in storing and handling the notified chemical.

The notified chemical is a dyestuff to be used on leather intended for furniture manufacture. Skin and eye contact may result during contact of articles coloured with the dye if it is not 100% bound to the substrate. However, as the dyed leather is resin coated in contact areas, and the notifier claims that the dye is chemically bound to the leather, significant public exposure to the notified chemical is unlikely.

13. RECOMMENDATIONS

To minimise occupational exposure to Sandoderm Black R the following guidelines and precautions should be observed:

- . good general and local exhaust ventilation should be provided in weighing areas;
- . particular care should be taken to avoid spillage or splashing of the dye solution;
- . production of mists in the workplace during mixing operations should be avoided;
- . good personal hygiene should be practiced to minimise the potential for ingestion; and
- . when handling the dye personal protective equipment which conforms to and is used in accordance with Australian Standards (AS) for eye protection (AS 1336, AS 1337) (13,14), impermeable gloves (AS 2161) (12) protective clothing (AS 3765.1, 3765.2) (15,16) and, if there is any possibility of dust generation, respiratory protection (AS 1715) (17), should be worn.

14. MATERIAL SAFETY DATA SHEET

The attached MSDS for Sandoderm Black R was provided in suitable format.

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of Sandoderm Black R 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

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12. Australian Standard 2161-1978, *Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)*, Standards Association of Australia Publ., Sydney, 1978.
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15. Australian Standard 3765.1-1990, *Clothing for Protection Against Hazardous Chemicals, Part 1: Protection Against General or Specific Chemicals*, Standards Association of Australia Publ., Sydney, 1990.

16. Australian Standard 3765.2-1990, *Clothing for Protection Against Hazardous Chemicals, Part 2: Limited Protection Against Specific Chemicals*, Standards Association of Australia Publ., Sydney, 1990.
17. Australian Standard 1715-1991, *Selection, use and maintenance of Respiratory Protective Devices*, Standards Association of Australia Publ, Sydney 1991.
18. N.I. Sax and R.J. Lewis, *Dangerous Properties of Industrial Materials*, Van Nostrand Reinhold, New York, 1989

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