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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Solsperse 28000

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FULL PUBLIC REPORT**Solsperse 28000****1. APPLICANT**

Orica Australia Pty Ltd of 1 Nicholson Street MELBOURNE VIC 3000 (ACN 004 145 888) has submitted a Limited Notification statement in support of their application for an assessment certificate for Solsperse 28000.

2. IDENTITY OF THE CHEMICAL

The chemical name, molecular and structural formulae, molecular weight, spectral data, and details of the polymer composition have been exempted from publication in the Full Public Report and the Summary Report.

Marketing Name: Solsperse 28000

Other Name(s): Substance S159470

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa: Solsperse 28000 is a brown viscous liquid.

Boiling Point: Not determined as the polymer decomposes before reaching boiling point (thermal decomposition point is above 340°C)

Relative Density: 0.94

Vapour Pressure: Not volatile, by analogy with similar polymers of high molecular weight and boiling point.

Water Solubility at 23°C: 30 mg/L

Partition Co-efficient (n-octanol/water): No data available – see comments below.

Hydrolysis as a Function of pH: No data available – see comments below.

Adsorption/Desorption:	No data available – see comments below.
Dissociation Constant:	No data available - see comments below.
Flash Point:	236°C
Flammability Limits:	No data available; the polymer is combustible, not flammable.
Autoignition Temperature:	No data available; the polymer is combustible, not flammable.
Explosive Properties:	No data available; expected to be stable under normal use conditions.
Reactivity/Stability:	The polymer is stable but should be segregated from oxidising agents.

Comments on Physico-Chemical Properties

The notifier claims, via analogue data for a similar polymer, that the notified polymer is not volatile. The very high molecular weight supports this assertion.

For environmental considerations the polymer is classified as having moderate water solubility (Mensink BJWG Montforts M et al 1995). Water solubility was determined to be 30 mg/L using a turbidometric method, whereby the turbidity of increasing dilutions of the dispersed polymer are plotted against the polymer concentration and at the concentration where the turbidity “plateaus” (i.e. no further significant turbidity decrease with dilution), the polymer is assumed to be truly soluble. This concentration is taken as the true water solubility.

The polymer contains ester and amide groups that could undergo hydrolytic cleavage under extreme pH. Since environmental pH ranges between 4 and 9, hydrolysis of the polymer is unlikely.

In contrast to its solubility in water, the polymer would be expected to be highly soluble in n-octanol. This indicates that the polymer has a tendency towards being lipophilic.

The notifier has not provided an adsorption/desorption value but has indicated that the polymer would be expected to associate with soil and sediment. From the information provided this statement cannot be confirmed. However, the polymer should have a slight tendency to adsorb onto surfaces in soil and sediments. Dispersant polymers have a tendency to bind to organic material within soils and sediments (Guiney PD McLaughlin JE Hamilton JD 1997).

No dissociation constant has been provided. The polymer is an amine salt and would be expected to dissociate in water. The molecule contains some free amine functionality with an expected pKa between 9 and 10.

4. PURITY OF THE CHEMICAL

Degree of Purity: 95.9%

Hazardous Impurities: None

**Non-hazardous Impurities
(> 1% by weight):**

Chemical name: Free fatty acids

Weight percentage: 3.7

Additives/Adjuvants: None

5. USE, VOLUME AND FORMULATION

Solsperse 28000 is a polymeric dispersant used in solvent based automotive and industrial paints.

Solsperse 28000 will not be manufactured in Australia. It will be imported neat in steel pails and drums of 20, 25 and 200L capacity. Annual import of the polymer is one tonne in the first year, increasing to up to 10 tonne by year five.

Solsperse 28000 will be distributed to 10-20 coatings manufacturers throughout Australia. The notified polymer will be present at up to 3% in coating products.

Coatings Manufacture

The coatings will be batch processed. The polymer will be added to a blending mixer with pigment(s), resin and solvent and blended at high speed to produce a mill base. The mill base is pumped to a large mixing vessel where the remaining resin and additives are mixed in by direct pumping. The batch will be tested for quality control purposes and adjusted. Once the desired coating properties are achieved, the finished product is filtered, then packaged into steel pails and drums of 20 L and 200 L capacity, respectively.

Coatings Application

The main uses for the paints/coatings containing the notified polymer will be automotive and industrial (household appliances, drum coatings, pipelines, can coatings and aluminium cladding). The paints are likely to be used Australia wide at up to 100 sites. The paints will be applied by either spraying, roller coating or dipping. Each entails a heat curing period after the paint has been applied. The coatings will be applied in booths or factories with good filtered exhaust ventilation systems, which should prevent fugitive loss of any polymer.

Within Australia, the containers will be transported by either road or rail.

6. OCCUPATIONAL EXPOSURE

Workers who may receive exposure to the notified polymer include transport and storage workers, coatings manufacture, and coatings applicators.

<i>Nature of Work Done</i>	<i>Number of Workers Exposed</i>	<i>Maximum Duration of Exposure: Hours per day/Days per year</i>
Transport and Storage	10	*/200
Coatings Manufacture:		
Mixing & dispersion;	40	4/30
Makeup;	40	2/30
QC testing;	10	8/30
Filtering and Packaging.	40	8/30
Coatings Application:		
addition to coater trays;	10	8/200
spray painting;	20	8/200
cleaning of equipment.	30	2/200

* data on hours per day was not provided.

Transport and Storage

After importation the notified polymer solution will be transported to the notifier's site and stored in original containers in a bonded licensed dangerous goods storage site. Repackaging is not envisaged. The products will be distributed to manufacturing sites by road. Both the notified polymer preparations and the reformulated products will be packed in steel pails or drums.

Transport and storage workers would only be exposed to the notified polymer in the case of an accident spill.

Coatings Manufacture

The notified polymer presents as a viscous, tacky liquid and following manual addition to a high speed shear mixer is blended with other ingredients. Spillages may occur during high speed dispersing and batch adjustment and testing. Occupational exposure to coatings formulations containing the notified polymer (at up to 3%) may occur through direct skin contact. All workers involved in the coatings manufacture process are required to wear personal protective equipment, namely impervious gloves, overalls and eye protection are required as a minimum. Exhaust ventilation is fitted in the formulation sites to capture volatiles at source. Inhalation exposure is unlikely given the viscous nature of the polymer.

The filtration and filling procedures are enclosed, automated systems. Skin contact is possible where operator attention is required if overfilling and spillage were to occur.

Waste polymer and formulations containing up to 3% polymer at formulation sites are collected and disposed of by licensed waste disposal contractors. Clean-up and maintenance workers may be exposed to residual paint products in the equipment.

Coatings Application

There are three types of paint application for the products containing the notified polymer namely spray and roller coating and dipping.

Spray painting has a high potential for occupational exposure and 80% of the polymer will be used in this manner. Typically the spray painter will measure out the components required in a particular formulation, including the pre-prepared paint containing the notified polymer, into an open container and pour this mixture into a spray gun. Spray painting operations and plant will be subject to the relevant spray painting legislation promulgated by the States and Territories. Spray painters wear personal protective equipment at all times; gloves and overalls while mixing the paint, and, in addition, a full face shield and respirator while spraying.

Roller coating application is usually performed in a booth like that used in spray painting. Aerosols are unlikely to be generated during roller coating. Painters will wear personal protective equipment including overalls, gloves and safety spectacles (or goggles) while mixing and applying the paint, and a cartridge respirator if volatile solvents are used.

Coating application by dipping into a large container or trough can be performed manually or by use of mechanical equipment. Painters do not manually insert individual objects into the paint. Usually, objects are fitted to a holder or frame lowered manually or automatically into the paint. Some splashing may occur during this process. Dipping applicators will wear overalls, gloves and eye protection.

Residual paint will be washed from the equipment manually, using recycled paint solvent, and the washings will be disposed of by solvent recyclers.

Once residual final paint mixture has dried, the notified polymer will be irreversibly bound within the cured matrix. It will not be separately available for either worker exposure, or dermal absorption.

7. PUBLIC EXPOSURE

Exposure of the general public as a result of manufacture, transport and disposal of the product containing notified polymer is assessed as being negligible. Coating products containing the notified polymer are to be used in a variety of industrial applications. The notified polymer and products containing it will not be available to the public. The general public may make dermal contact with cured paint products on automobiles and packaging products.

8. ENVIRONMENTAL EXPOSURE

Release

There is potential for loss of the polymer during paint manufacture due to spills, drum residuals and equipment cleaning. Approximately 80 kg per annum will be lost from equipment cleaning, 20 kg per annum from spills and up to 50 kg per annum as residues in empty containers. This waste will be collected by licensed waste contractors and is likely to be disposed of to landfill.

Each method of coating application has a degree of loss of material. The notifier estimates that 80% (8 tonnes per annum) of the polymer will be used in the spray application. During spray painting the loss due to over-spray has been given as 40% (3.2 tonnes per annum). The remaining 20% (2 tonnes per annum) of the polymer will be used for roller coating of cans and cladding. For roller application the loss has been given as 15%, 150 kg per annum from equipment cleaning, 50 kg per annum due to spills and 100 kg per annum left as residues in the empty paint cans.

Therefore, up to 3.65 tonnes of waste will be generated annually from all the user sites combined. This waste will also be collected by licensed waste contractors and likely be disposed of to landfill.

Fate

The fate of the polymer will be the same as the coated article, i.e. either recycled or sent to landfill. During the recycling process the coating (incorporating the polymer) will be removed and become part of a solid/sludge waste that will go to landfill, to incineration, or destroyed during smelting of the metal. Incineration of the paint film would emit noxious fumes including oxides of carbon and nitrogen.

The solid waste generated in the manufacturing, formulation and application of the coating will be disposed of to landfill. Leaching of the polymer from landfill is unlikely because of its water solubility and potential soil affinity.

The polymer is not expected to cross biological membranes due to its high molecular weight and moderate solubility, therefore it is not expected to bioaccumulate (Connell DW 1989).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary reports only were available for investigations into the acute toxicity of the notified polymer, Solsperse 28000. The notified polymer is identified in the reports as Substance S159470.

Summary of the acute toxicity of Solsperse 28000.

<i>Test</i>	<i>Species</i>	<i>Outcome</i>
Acute oral toxicity	Rat	LD ₅₀ > 2 000 mg/kg
Skin irritation	Rabbit	Slight irritant
Eye irritation	Rabbit	Mild irritant
Skin sensitisation	Mouse	Not a moderate - strong sensitiser

9.1.1 Oral Toxicity (Zeneca Central Toxicology Laboratory 1993)

<i>Species:</i>	Rat
<i>Number/sex of animals:</i>	5/sex
<i>Observation period:</i>	15 days
<i>Method of administration:</i>	2 000 mg/kg administered in corn oil.
<i>Test method:</i>	Not stated
<i>Mortality:</i>	Nil
<i>Clinical observations:</i>	No significant signs of systemic toxicity.
<i>Morphological findings:</i>	No treatment related findings.
<i>LD₅₀:</i>	> 2 000 mg/kg
<i>Result:</i>	The notified polymer was of very low acute oral toxicity in rats.

9.1.2 Skin Irritation (Zeneca Central Toxicology Laboratory 1993)

Species: Rabbit

Number/sex of animals: 3 males

Observation period: 3 days

Method of administration: Not stated.

Test method: Not stated.

Draize scores:

<i>Time after treatment (hours)</i>	<i>Animal #</i>		
	<i>1</i>	<i>2</i>	<i>3</i>
<i>Erythema</i>			
0.5 – 1.0	^a 0	1	1
24	1	0	1
48-72	0	0	1
<i>Oedema</i>			
0.5 – 1.0	0	1	0
24	1	0	1
48-72	0	0	0

^a see Attachment 1 for Draize scales

*Individual mean scores
(24, 48, 72 hours):*

Erythema: 0.3, 0.0, 0.7;
Oedema: 0.3, 0.0, 0.3.

Cutaneous reactions:

The very slight erythema (Grade 1) and very slight oedema (Grade 1) observed from time of administration had resolved by the end of the observation period.

Result:

The notified polymer was slightly irritating to rabbit skin.

9.1.3 Eye Irritation (Zeneca Central Toxicology Laboratory 1993)

Species/strain: Rabbit

Number/sex of animals: 3 females

Observation period: 4 days

Method of administration: Not stated.

Test method: Not stated.

Draize scores of unirrigated eyes:

	<i>Time after instillation (hours)</i>														
<i>Animal #</i>	<i>1.0</i>			<i>24</i>			<i>48</i>			<i>72</i>			<i>96</i>		
<i>Cornea</i>	<i>All individual scores were zero</i>														
<i>Iris</i>	<i>All individual scores were zero</i>														
<i>Conjunctiva</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>	<i>r</i>	<i>c</i>	<i>d</i>
1	1 ^a	0	2	0	0	1	0	0	0	0	0	0	-	-	-
2	1	0	2	1	0	2	1	0	1	1	0	1	0	0	0
3	1	0	1	1	0	1	1	0	1	1	0	0	0	0	0
^a see Attachment 1 for Draize scales. r = redness c = chemosis d = discharge															

Mean individual scores (24, 48, 72 hours): Chemosis: 0.0, 0.0, 0.0;
Conjunctival redness: 0.0, 1.0, 1.0.

Ocular response: Slight conjunctival redness and slight to moderate discharge, both resolving by day 4.

Result: The notified polymer was slightly irritating to rabbit eyes.

9.1.4 Sensitisation potential – Mouse Local Lymph Node Assay (LLNA) (Zeneca Central Toxicology Laboratory 1993)

<i>Concentration of Test Sample</i>	<i>CPM/Lymph node ($\times 10^{-2}$) $^3\text{H-TdR}$</i>	<i>Test/Control Ratio*</i>
Vehicle (acetone)	1.37	N/A
1% w/v	0.75	0.55
3% w/v	0.68	0.50
10% w/v	0.80	0.58

A test/control ratio ≥ 3.0 indicates a positive LLNA result (prediction, a sensitiser);

A test/control ratio ≤ 3.0 indicates a negative LLNA result (prediction, unlikely to be a strong sensitiser) (Basketter et al 1991, *Toxicology Methods* 1(1)30-43; Kimber et al 1991, *Toxicology Letters* 55:203-213).

Comment: Evidence of induction of T-cell proliferation was not observed with the test substance as the incorporation of tritiated thymidine into the lymph node at each test concentration was less than that of the vehicle control.

Result: The notified polymer was not shown to be a moderate or strong sensitiser under the conditions of the test.

9.2 Genotoxicity

Bacterial Reverse Mutation Assay (Zeneca Central Toxicology Laboratory 1993)

Strains: *S. typhimurium*: TA 1535, TA 1537, TA 98, TA 100;
E. coli: WP2P, WP2PuvrA.

Auxillary metabolising system: Liver fraction (S9) from rats pretreated with phenobarbital and β -naphthaflavone.

Concentration range: 0, 100, 200, 500, 1 000, 2 500, 5 000 $\mu\text{g}/\text{plate}$.
Each concentration was tested in triplicate, with or without metabolic activation, in two independent experiments.
Appropriate strain specific positive control reference substances were used.

Test method: OECD TG 471 & 472 – plate incorporation method ((OECD 1995-1996)).

Comment: Precipitation was noted at 5 000 $\mu\text{g}/\text{plate}$ in Experiment 1. Precipitation was noted at and above 2 500 $\mu\text{g}/\text{plate}$ in Experiment 2. No toxicity was observed. There were no significant increases in revertant colony numbers at any concentration, in the presence or absence of metabolic activation. Concurrent positive controls used in the test induced marked increases in the frequency of revertant

colonies and the activity of the S9 fraction was found to be satisfactory.

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

9.3 Overall Assessment of Toxicological Data

The notified polymer is of very low acute oral toxicity ($LD_{50} > 2\,000$ mg/kg) in rats. Testing for irritant properties in rabbits shows it is a slight skin and eye irritant. Screening for skin sensitisation potential using the local lymph node assay (LLNA) indicates that the polymer is unlikely to be a moderate to strong sensitiser. However, the OECD test guideline for skin sensitisation (406) recommends that negative findings in the LLNA be confirmed with adjuvant (guineapig maximisation test) or non-adjuvant type (Buehler test) testing. Confirmatory test data was not provided for the polymer.

The notified polymer was non mutagenic in a bacterial test system.

Based on the available data, the notified polymer would not be classified as a hazardous substance under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1999) for the toxicological end points investigated, excluding skin sensitisation. In the latter instance the data is inadequate to enable classification.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Once the paint/coating is applied, the polymer will be incorporated in an inert film and consequently should not present a hazard. Any chips, flakes or fragments formed by mistreatment or general wear and tear will be inert. The paint will slowly deteriorate due to exposure to UV light and other abiotic processes, but this will be insignificant.

The majority of waste containing the polymer will be generated during the manufacture and use of the coatings. This waste will be disposed of to landfill, or by incineration. As indicated above, the polymer is unlikely to leach from landfill due to its solubility and likely affinity to soil. The majority of the polymer will be present within the cured inert coating matrix and therefore will be unavailable for leaching.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer is of very low acute oral toxicity to the rat and is slightly irritating to rabbit eyes and skin. The notified polymer is unlikely to be a moderate to strong sensitiser to skin as evidenced by the findings in the local lymph node assay. However, confirmatory evidence that the notified chemical was non sensitising would be required as agents that induce a weak sensitisation reaction are unlikely to be detected by this assay. The notified polymer was non mutagenic in a bacterial test system.

Based on the available data, the notified polymer would not be classified as a hazardous substance under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1999) for the toxicological end points investigated, excluding skin sensitisation. In the latter instance the data is inadequate to enable classification.

Occupational Health and Safety

Exposure to the notified polymer may occur during coating manufacture and coating applications. During these processes where manual handling is required, exposure is most likely to occur from skin (predominantly) and eye contact with the neat notified polymer as it is incorporated during coatings manufacture, and from exposure to coatings preparations that contain the notified polymer at up to 3%. Exposure, and any potential for skin and eye irritation during formulation will be mitigated by the presence of engineering controls, such as closed systems and the requirement for workers to wear personal protective equipment, such as impervious gloves, overalls and eye protection. The risk of skin and eye irritation from the notified polymer during coatings application is considered negligible given that the polymer will be present at a maximum of 3%, the presence of in situ engineering controls and the requirement that personal protective equipment be worn.

Public Health

Exposure of the general public as a result of transport and disposal of the notified polymer and manufacture of products containing it is assessed as being negligible. The notified polymer is not available for sale to the general public and will only be used in coating products used in industrial applications. Members of the public may make dermal contact with items such as automobiles coated with products containing the notified polymer. However, the risk to public health from the notified polymer will be negligible because the polymer is bound within a cured coating or ink film, from which it is unlikely to be bioavailable.

13. RECOMMENDATIONS

To minimise occupational exposure to the notified polymer the following practices and guidelines should be observed:

- Workers should receive regular instruction on good occupational hygiene practices in order to minimise personal contact, and contamination of the work environment with the notified polymer and the products that contain it.
- Personal protective equipment should be used where exposure to the notified polymer and the products that contain it occurs. Workers should be trained in the proper fit, correct use and maintenance of their protective gear. Guidance in the selection, personal fit and maintenance of personal protective equipment can be obtained from:

Protective eyewear: AS 1336 (SAA 1994)
AS/NZS 1337 (SAA/SANZ 1992).

Chemical impermeable clothing: AS 3765.2 (SAA 1990).

Impermeable gloves: AS 2161.2 (SAA/SANZ 1998).

Occupational footwear: AS/NZS 2210 (SAA/SANZ 1994).

- Workplace practices and control procedures consistent with provisions of State, Territory and Commonwealth legislation based on the *National Model Regulations for the Control of Workplace Hazardous Substances* must be in operation if products containing the notified polymer are determined to be hazardous.
- Practical guidance on achieving a safe working environment for spray painting, and compliance with the Provisions of State, Territory and Commonwealth legislation based on the *National Model Regulations for the Control of Workplace Hazardous Substances* (NOHSC 1994) and the *National Standard for Plant* (NOHSC 1994) can be found in *National Guidance Material for Spray Painting* (NOHSC 1999).
- A copy of the MSDS for the notified polymer and the products that contain it should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for Solspers 28000 was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 1994).

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical may 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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Zeneca Central Toxicology Laboratory (1993). Substance S159470 Local lymph Node Assay Study # CTL/T/5295. Macclesfield.

Zeneca Central Toxicology Laboratory (1993). Substance S159470 Acute Oral Toxicity Study to the Rat, Study # CTL/L/5306. Macclesfield.

Zeneca Central Toxicology Laboratory (1993). Substance S159470 Eye Irritation Study in the Rabbit CTL/L/5280. Macclesfield.

Zeneca Central Toxicology Laboratory (1993). Substance S159470 Skin Irritation Study in the Rabbit, Study # CTL/L/5281. Macclesfield.

Attachment 1

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

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

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

CORNEA

<i>Opacity</i>	<i>Rating</i>	<i>Area of Cornea involved</i>	<i>Rating</i>
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		

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<i>Redness</i>	<i>Rating</i>	<i>Chemosis</i>	<i>Rating</i>	<i>Discharge</i>	<i>Rating</i>
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

<i>Values</i>	<i>Rating</i>
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