File No: NA/336

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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME**

**FULL PUBLIC REPORT**

**NIAX Y-10656**

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

## NIAX Y-10656

## 1. APPLICANT

Osi Specialties (Australia) Pty Limited of 1st floor, 1002 High Street ARMADALE VICTORIA 3143 has submitted a limited notification statement in support of their application for an assessment certificate for NIAX Y-10656.

## 2. IDENTITY OF THE CHEMICAL

NIAX Y-10656 is not considered to be hazardous based on the nature of the chemical and the data provided. Therefore the chemical identity, import volume and methods of detection have been exempted from publication in the Full Public Report and the Summary Report

| | |
|---|---|
| **Other names:** | alkylalkylsiloxane polymer |
| **Trade name:** | NIAX Y-10656 |
| **Number-average molecular weight (NAMW):** | < 1000 |

As the substance has 50% < 500 NAMW and 90% < 1000 NAMW, it does not meet the definition of a polymer under the Act.

## 3. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|---|---|
| **Appearance at 20°C and 101.3 kPa:** | clear to transparent pale liquid |
| **Boiling point:** | decomposes before boiling |
| **Specific gravity:** | 0.87 at 25° |
| **Vapour pressure:** | < 1.3 hPa at 25°C |
| **Water solubility:** | insoluble |
| **Partition co-efficient (n-octanol/water):** | not provided |

| | |
|---|---|
| **Hydrolysis as a function of pH:** | not provided |
| **Adsorption/Desorption:** | not provided |
| **Dissociation constant:** | not provided |
| **Flash point:** | 90°C |
| **Flammability limits:** | not determined |
| **Autoignition temperature:** | not determined |
| **Explosive properties:** | none |
| **Reactivity/Stability:** | stable, incompatible with oxidising agents and nitric acid |

**Comments on Physico-Chemical Properties**

The notifier has stated that the notified substance is immiscible, ie the notified substance and water do not mix at all. From the chemical's structure it is likely that the substance will be insoluble. Silicones are noted for being extremely hydrophobic (1). The notifier also claims that the imported product containing the notified substance will be insoluble in water.

Whilst hydrolysis was not determined, the notified substance does not contain any readily hydrolysable groups. This, along with the substance's insolubility in water, makes hydrolysis under environmental conditions unlikely.

As siloxanes are generally regarded as surface active agents (1), partition coefficients are not particularly relevant.

Adsorption to sediments is likely, based on the surface tension and low solubility of organosilicones (2). Thus, the substance is likely to be essentially immobile in soils. (Here it is expected to undergo rapid and extensive degradation to form water soluble products (3)).

## 4. PURITY OF THE CHEMICAL

| | |
|---|---|
| **Degree of purity:** | < 100% |
| **Toxic or hazardous impurities:** | none |
| **Non-hazardous impurities (> 1% by weight):** | there are a number of impurities each with <1% of the total composition |
| **Additives/Adjuvants:** | none |

## 5. USE, VOLUME AND FORMULATION

NIAX Y-10656 will be imported as a component of a surface active agent (at a concentration of < 12%) used in the manufacture of flexible polyurethane foam. The notified chemical will be imported in 205 L steel drums at a volume of up to one tonne per year over the next five years.

## 6. OCCUPATIONAL EXPOSURE

The notified chemical will be imported at a concentration of < 12% within a silicone surfactant in 205 L drums. These will be transported by road to the polyurethane foam manufacturing facility and stored until required. There is not anticipated to be any exposure to the notified chemical except in the event of a spill.

To manufacture the polyurethane foam, the notified chemical within the surfactant will be pumped into feed tanks. The surfactant will be fed into a closed mixing vessel which will automatically produce the solid polyurethane foam, cross-linking and encapsulating the notified chemical at a final concentration of < 0.12%. The manufacturing will be complemented by mechanical ventilation. This procedure will be monitored by four operators who are specifically trained in polyurethane foam production. As the manufacture of polyurethane foam is a continuous process, it can be estimated that workers will be potentially exposed to the notified chemical for 8 hours a day, 5 days per week. There should not be any significant exposure to the notified chemical after the production of the polyurethane foam. The foam will be used to supply the furniture industry.

## 7. PUBLIC EXPOSURE

The notified polymer will enter the public domain in fixed form as a component of polyurethane foams in furniture. Although public contact with the foam may occur, the notified chemical is chemically fixed to the foam, minimising its potential for absorption. There may be a limited potential for public contact with the notified chemical as a component of polyurethane foam in discarded furniture at waste disposal/landfill facilities, but it seems unlikely that this would be a significant public health hazard due its chemical fixation to the foam. It is expected to degrade slowly

at landfill sites. If these articles are disposed of by incineration, the notified chemical would release oxides of carbon and silicon, and water vapour.

## 8. ENVIRONMENTAL EXPOSURE

### Release

The notified substance is an ingredient for polyurethane manufacture, thus the potential for environmental exposure is limited to shipping, formulation and polyurethane foam manufacture.

The manufacturing process is a continuous automatic process with the notified substance constituting < 0.12% of the polyurethane foam. The substance is part of a product that is chemically fixed into solid polyurethane foam by the cross-linking process. Given the low concentration of the notified substance plus the cross-linking, no release of the notified substance is envisaged.

Drum residues are estimated at less than 0.2 L per 205 L drum. Residues will be collected and disposed of by incineration.

Off-cuts of the foam are recycled into the rebond area where they are used to make carpet underlay.

### Fate

Most of the notified substance is chemically fixed during formulation of polyurethane foam. Therefore its fate is tied to the fate of the foam. The foam is likely to end up in landfill where it will very slowly degrade.

Incineration of the notified substance will result in oxides of carbon and silicon, and water vapour.

The molecular weight of the monomer is of the size that would allow passage across biological membranes and the n-octanol/water coefficient is expected to be high due to the low water solubility. These characteristics indicate a moderate to strong potential for bioaccumulation. However, the bioavailability of the notified substance is expected to be low as following introduction to water silicones are lost to the atmosphere, where they will decompose, or adsorbed onto sediments. Here they are believed to become permanent, inert components of the sediments (1). In terrestrial environments, silicone fluids are not believed to be persistent and are extensively degraded/rearranged to form water soluble products (1,3).

Contaminated packaging will be disposed of according to state and local government regulations.

## 9. EVALUATION OF TOXICOLOGICAL DATA

No toxicity studies have been performed on the notified chemical as toxicological data are not required for chemicals with an import volume of < 1 tonne/year according to the Act. However, toxicity studies have been submitted and accepted on an analogous compound, trisiloxane, on the basis of structural similarity to NIAX Y-10656.

### 9.1 Acute Toxicity

**Summary of the acute toxicity of Trisiloxane**

| *Test* | *Species* | *Outcome* | *Reference* |
|---|---|---|---|
| acute oral toxicity | rat | low oral toxicity | 4 |
| acute dermal toxicity | rat | low dermal toxicity | 4 |
| skin irritation | rabbit | non irritant | 4 |
| eye irritation | rabbit | non irritant | 4 |
| skin sensitisation | guinea pig | not performed | - |

#### 9.1.1 Oral Toxicity (4)

| | |
|---|---|
| *Species/strain:* | Sprague Dawley albino rats |
| *Number/sex of animals:* | 5 males/5 females |
| *Observation period:* | 14 days |
| *Method of administration:* | the analogue was administered by preoral intubation at a dose of 5000 mg/kg; after 14 days the rats were sacrificed and necropsied |
| *Clinical observations:* | no clinical signs of toxicity; most rats exhibited a weight gain during the 14 day observation period |
| *Mortality:* | none |
| *Morphological findings:* | none |
| *Test method:* | according to OECD guidelines (5) |
| $LD_{50}$*:* | > 5000 mg/kg |
| *Result:* | the analogue was not toxic by acute oral administration |

### 9.1.2 Dermal Toxicity (4)

| | |
|---|---|
| *Species/strain:* | New Zealand White rabbits |
| *Number/sex of animals:* | 5 males/5 females |
| *Observation period:* | 14 days |
| *Method of administration:* | undiluted liquid analogue was applied to the clipped intact skin at 2000 mg/kg for 24 hours under occlusive dressing; after 24 hours the dressings were removed and observed frequently for signs of toxic effects; after 14 days all animals were sacrificed and necropsied |
| *Clinical observations:* | mild erythema and oedema observed at day 1 in all rabbits; most rabbits exhibited a consistent weight gain during the 14 day observation period |
| *Mortality:* | none |
| *Morphological findings:* | none |
| *Test method:* | according to OECD guidelines (5) |
| $LD_{50}$*:* | > 2000 mg/kg |
| *Result:* | the analogue was not toxic by acute dermal administration |

### 9.1.3 Inhalation Toxicity

not performed

### 9.1.4 Skin Irritation (4)

*Species/strain:* New Zealand White rabbits

*Number/sex of animals:* 3 males/3 females

*Observation period:* 7 days

*Method of administration:* 0.5 mL of the undiluted analogue was applied to the clipped intact dorsal trunk skin of the rabbits and maintained under an occlusive dressing for 4 hours; after the contact period, the covering and excess analogue were removed and skin readings made at 1, 24, 48 and 72 hours and at 7 days according to Draize (6)

*Draize scores[i] (6):*

| ***Time after treatment (hours)*** | ***Animal #*** | | | | | |
|---|---|---|---|---|---|---|
| | ***1*** | ***2*** | ***3*** | ***4*** | ***5*** | ***6*** |
| ***Erythema*** | | | | | | |
| 1 | 1 | 0 | 0 | 1 | 1 | 1 |
| 24 | 0 | 0 | 0 | 1 | 0 | 0 |
| 48 | 0 | 0 | 0 | 0 | 0 | 0 |
| 72 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7 days | 0 | 0 | 0 | 0 | 0 | 0 |
| ***Oedema*** | | | | | | |
| 1 | 1 | 0 | 0 | 0 | 0 | 0 |
| 24 | 0 | 0 | 0 | 0 | 0 | 0 |
| 48 | 0 | 0 | 0 | 0 | 0 | 0 |
| 72 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7 days | 0 | 0 | 0 | 0 | 0 | 0 |

[i]see Attachment 1 for Draize scales

*Test method:* according to OECD guidelines (5)

*Result:* the analogue is not a skin irritant

### 9.1.5 Eye Irritation (4)

*Species/strain:* New Zealand White rabbits

*Number/sex of animals:* 3 males/3 females

*Observation period:* 7 days

*Method of administration:* 0.1 mL of the undiluted analogue was instilled into the lower conjunctival sac of one eye of each of the six rabbits, the undosed eye serving as a control; readings were made at 1, 24, 48 and 72 hours and at 7 days following instillation; fluorescein staining was performed at day 1 and each subsequent examination day, grading and scoring being conducted according to Draize (6)

*Draize scores[i] (6) of unirrigated eyes:*

| | ***Time after instillation*** | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ***Animal*** | ***1 hour*** | | | ***24 hours*** | | | ***48 hours*** | | | ***72 hours*** | | | ***7 days*** | | |
| ***Cornea*** | ***o[a]*** | ***a[b]*** | | ***o[a]*** | ***a[b]*** | | ***o[a]*** | ***a[b]*** | | ***o[a]*** | ***a[b]*** | | ***o[a]*** | ***a[b]*** | |
| 1 | 0 | 0 | | 0 | 0 | | 0 | 0 | | 0 | 0 | | 0 | 0 | |
| 2 | 0 | 0 | | 0 | 0 | | 0 | 0 | | 0 | 0 | | 0 | 0 | |
| 3 | 0 | 0 | | 0 | 0 | | 0 | 0 | | 0 | 0 | | 0 | 0 | |
| 4 | 0 | 0 | | 0 | 0 | | 0 | 0 | | 0 | 0 | | 0 | 0 | |
| 5 | 0 | 0 | | 0 | 0 | | 0 | 0 | | 0 | 0 | | 0 | 0 | |
| 6 | 0 | 0 | | 0 | 0 | | 0 | 0 | | 0 | 0 | | 0 | 0 | |
| ***Iris*** | | | | | | | | | | | | | | | |
| 1 | 0 | | | 0 | | | 0 | | | 0 | | | 0 | | |
| 2 | 0 | | | 0 | | | 0 | | | 0 | | | 0 | | |
| 3 | 0 | | | 0 | | | 0 | | | 0 | | | 0 | | |
| 4 | 0 | | | 0 | | | 0 | | | 0 | | | 0 | | |
| 5 | 0 | | | 0 | | | 0 | | | 0 | | | 0 | | |
| 6 | 0 | | | 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 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 4 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5 | 1 | 0 | 2 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

[i] see Attachment 1 for Draize scales

[a] opacity [b] area [c] redness [d] chemosis [e] discharge

| | |
|---|---|
| *Test method:* | according to OECD guidelines (5) |
| *Result:* | there was minor conjunctival redness with minor to moderate ocular discharge in all six rabbits, however the effects were not severe enough to classify the analogue as an eye irritant |

### 9.1.6 Skin Sensitisation

not performed

## 9.2 Repeated Dose Toxicity

not performed

## 9.3 Genotoxicity

### 9.3.1 Salmonella typhimurium Reverse Mutation Assay (4)

| | |
|---|---|
| *Strains:* | TA98, TA100, TA1535, TA1537, TA1538 |
| *Concentration range:* | 0.1 to 5.0 mg/plate in the presence and absence of metabolic activation by S9 rat liver |
| *Test method:* | according to OECD guidelines (5) |
| *Result:* | no mutagenic activity was observed in any strain in the presence or the absence of S9; the analogue is not a genotoxin |

## 9.4 Overall Assessment of Toxicological Data

In accepting the analogue toxicological data as being representative of that of the notified chemical, it can be inferred that NIAX Y-10656 is unlikely to be toxic by acute oral administration in rats or dermal administration in rabbits, however mild dermal erythema and oedema were noticed in all rabbits during the dermal toxicity study. It is also unlikely to be a skin or eye irritant in rabbits, and is not expected to have any bacterial mutagenic effect.

The notified chemical is not classified as hazardous according to Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances (7).*

## 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Ecotoxicological data are not required for chemicals that will have a small (< 1 tonne/year) import volume according to the Act.

However, a fish toxicity report was submitted for a substance that is structurally analogous to that of the notified substance.

The test was performed following TSCA Guideline 797.1400 (8). Nominal concentrations of 15 - 110 mg/L were tested. All test solutions were observed to be very cloudy (white in colour) with a thin oil layer, indicating that the test material's limit of water solubility had been exceeded. It must be noted that this analogous substance is likely to have a somewhat lower water solubility than that of the notified substance due to its longer carbon chain.

Silicone fluids in intimate contact with soil undergo siloxane bond redistribution and hydrolysis, resulting in the formation of cyclic and linear oligomers (9). Cyclic oligomers will include octamethylcyclotetrasiloxanes, and toxicity figures are presented below (10).

| ***Test*** | ***Species*** | ***Results*** |
|---|---|---|
| acute toxicity (Flow-Through) | Fathead Minnow (*Pimephales promelas*) | 96 hr $LC_{50}$ > 110 mg/L (NOEC = 110 mg/L) |
| acute toxicity medium: | Midge (*Chironomus tentans)* | NOEC |
| Water Only | | 15 µg/L |
| Sediment - Low organic content | | 65 mg/L |
| Sediment - Medium organic content | | 120 mg/L |
| Sediment - High organic content | | 54 mg/L |

* NOEC - no observable effect concentration

The toxicity is clearly reduced in the presence of sediment or particulate organic carbon. Volatility serves as another avenue to limit aquatic exposure of low MW oligomers.

## 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The manufacture of the polyurethane foam is a continuous automatic process. Residues from drums are disposed of to an approved incineration facility. Off-cuts of the foam are recycled to make carpet underlay. The environmental hazard of the notified substance during the manufacturing stage is rated as low.

The environmental hazard from the notified substance, once incorporated into the polyurethane foam, is rated as negligible. The notified substance constitutes less than 0.12% of the foam formulation. It becomes chemically fixed within the foam by cross-linking.

Polyurethane foam consigned to landfill will physically break down over time. It is unlikely to leach and will remain in the landfill. The environmental hazard from the disposal of waste containing the substance is rated as low.

It is predicted that the notified substance may have a moderate to strong potential for bioaccumulation. As the chemical's environmental exposure through release to aquatic and terrestrial environments will be negligible, the environmental hazard associated with bioaccumulation is considered low.

Complete incineration of the substance will generate oxides of carbon and silicon, and water vapour. The environmental hazard can be rated as negligible.

The overall environmental hazard from the use of the substance is rated as low.

## 12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The toxicological data from the analogue for the notified chemical indicate that NIAX Y-10656 is unlikely to cause adverse health effects in humans through acute oral or dermal administration. It is not expected to be a skin or eye irritant, nor is it expected to cause any mutagenic effects.

The notified chemical will be imported at a concentration of < 12% within the imported formulation. In this form the notified chemical does not present any major physico-chemical concerns to workers.

The imported silicone surfactant containing the notified chemical will be handled in 205 L drums upon importation and transport to the manufacturing facility. There is not expected to be public or occupational exposure to the notified chemical except in the event of a spill, during which the procedures in the recommendations should be followed to minimise exposure.

At the polyurethane foam manufacturing site there will be the potential for dermal exposure during the line pumping of the surfactant into the reaction mixer through minor spillage or splashing. Workers involved in this procedure will wear PVC coated gloves, eye protection and protective clothing, which will also serve to reduce exposure to the notified chemical. The manufacture of the polyurethane foam will

not involve any worker exposure as it will take place within a closed system. Upon completion of the process the notified chemical will be encapsulated within the polyurethane foam at a concentration of < 0.12%, thus it is unlikely that there will be any significant exposure to foam manufacturers or furniture manufacturers utilising the foam.

There exists minimal possibility for direct public exposure to the notified chemical during normal use of the polyurethane foams in which it is incorporated, due to its chemical fixation by cross-linking and encapsulation in the foam.

## 13. RECOMMENDATIONS

To minimise exposure to NIAX Y-10656 the following guidelines and precautions should be observed:

- If engineering controls and work practices are insufficient to reduce exposure to NIAX Y-10656 to a safe level, then the following personal protective equipment which conforms to Australian Standards (AS) or Australian/New Zealand Standard (AS/NZS) should be worn;

    - safety goggles should be selected and fitted in accordance with AS 1336 (11) to comply with AS/NZS 1337 (12),

    - industrial clothing must conform with the specifications detailed in AS 2919 (13),

    - impermeable gloves or mittens conforming with AS 2161 (14),

- Spillage of the notified chemical should be avoided, any spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal by incineration according to national and local regulations;

- Good personal hygiene should be practised to minimise the potential for ingestion;

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

## 14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (15).

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 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. Hamelink, JL, 1992, Silicones, pp 383-394, in, Hutzinger, O & de Oude, NT (eds) 1992, *Handbook of Environmental Chemistry*, Vol 3: Part F, Anthropogenic Compounds: Detergents, Springer-Verlag, Berlin.

2 World Health Organisation, 1986, 'Reports and Studies No. 29. Review of Potentially Harmful Substances: Organosilicon Compounds (Silanes and Siloxanes)'.

3. Lehmann, RG, Varaprath, S, Annelin, RB and Arndt, JL, 1995, 'Degradation of Silicone Polymer in a Variety of Soils', *Environmental Toxicology and Chemistry,* **14:8**, pp. 1299-1305.

4. Bushey Run Research Center, 1995, *Acute Toxicity and Primary Irritancy Using the Rat (Preoral Toxicity Test) and the Rabbit (Cutaneous Ocular Tests),* Report 94N1491, data on file.

5. Organisation for Economic Co-operation and Development, *OECD Guidelines for Testing of chemicals*, OECD, Paris.

6. 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**.

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

8. US EPA, 1985, *Toxic Substances Control Act (TSCA) Test Guidelines*, Federal Register 50(188): 39252-39516.

9. Buch, RR & Ingebrigtson, DN, 1979, 'Rearrangement of Poly(dimethylsiloxane) Fluids on Soil', *Environmental Science and Technology*, **13**, pp. 676 - 679.

10. Kent, DJ, McNamara, PC, Putt, AE, Hobson, JF and Silberhorn, EM, 1994, 'Octamethylcyclotetrasiloxane in Aquatic Sediments: Toxicity and Risk Assessment', *Ecotoxicology and Environmental Safety*, **29**, pp. 372 - 389.

11. Standards Australia 1994, *Australian Standard 1336-1994*, *Eye protection in the Industrial Environment*, Standards Association of Australia Publ., Sydney.

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

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

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

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

## 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 |