File No: NA/541

December 1997

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

SikaSet AU

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

SikaSet AU

1. APPLICANT

Sika Australia Pty Limited of 55 Elizabeth Street WETHERILL PARK NSW 2164 has submitted a standard notification statement in support of their application for an assessment certificate for SikaSet AU.

2. IDENTITY OF THE CHEMICAL

SikaSet AU is considered to be hazardous based on the nature of the substance and the data provided. However, the type of hazard presented by this substance does not qualify it as a Type 1 ingredient (1, 2), and therefore the chemical identity need not be disclosed. Therefore the chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data and details of customers have been exempted from publication in the Full Public Report and the Summary Report.

Trade Names: SikaSet AU

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	brown powder
Melting Point:	> 1 500°C
Specific Gravity:	2.86
Vapour Pressure:	not provided
Water Solubility:	not provided (see comments below)
Partition Co-efficient (n-octanol/water):	not provided (see comments below)
Hydrolysis as a Function of pH:	not provided (see comments below)

Adsorption/Desorption: not provided (see comments below)

Dissociation Constant: not provided (see comments below)

Particle Size: median aerodynamic diameter = 10.12 μm

Flash Point: not provided

Flammability Limits: not provided

Autoignition Temperature: not provided

Explosive Properties: not provided

Reactivity/Stability: not provided; the notifier states that the substance is generally stable; on contact with water a reaction takes place, but this is not violent

Comments on Physico-Chemical Properties

The material is a fine powder which is not soluble in water. However, when mixed with water it undergoes irreversible hydration reactions with the formation of silicate and aluminate chain structures which can form strong physical links between the cement particles and particles of sand etc.

The cement does not undergo hydrolytic degradation.

The notified material contains no organic groups and would have no tendency to dissolve in oils or fats, and consequently the partition coefficient and the adsorption/desorption coefficient have no relevance for this material.

4. PURITY OF THE CHEMICAL

Degree of Purity: 99%

Toxic or Hazardous Impurities:

Name	*CAS Number*	*% Weight*
Crystalline silica	7631-86-9	< 1
Chromium	7440-47-3	0.08 (80 ppm)
Chromium (hexavalent)	Not applicable	0.002 (2 ppm)

Non-hazardous Impurities (> 1% by weight): trace amounts of free lime and salts may be present

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified substance will not be manufactured in Australia. SikaSet AU is a cement product that will be used as an additive for high performance concrete and cement preparations.

Annual imports of the notified substance are expected to be between 100 and 200 tonnes per annum, and to remain between these levels for the next five years.

6. OCCUPATIONAL EXPOSURE

Minimal exposure to the notified substance is expected when waterside and transport workers are moving and unloading pallets containing 25 kg bags of SikaSet AU. Warehouse workers will unload unopened bags from pallets, and arrange distribution of blended products to customer sites. Minimal exposure is also expected for these workers.

Blending operations will take place using a 1.5 tonne dry powder blender. SikaSet AU will be used as an additive to improve the performance of other concrete products, and will be added at a concentration of up to 33% to these products. Workers will manually open bags of the notified substance, and add the notified substance to a hopper. The blended powder will then be transferred directly to a filling machine and repacked in 25 kg bags. Dust will be generated by these processes, the majority of which will be collected in filters attached to an exhaust system. Dermal, inhalation and ocular exposure to SikaSet AU is likely during these blending operations. Given that the respirable mass fraction is 50% (particles less than 10 μm diameter (cited in (3)), and that almost all (greater than 97%) of the particles are in the range considered to be inspirable (cited in (3)), inhalation is expected to be the primary route of exposure.

Dermal, inhalation and ocular exposure is also expected when workers use the powdered form of the end-use concrete product. This will contain up to 33% of the notified substance. The notifier states that applicators will be used to apply the concrete/mortar products. Equipment information sheets for these applicators indicate that that these applicators are essentially closed systems, with dry mix or wet concrete added to a central hopper. This mix is then sprayed onto the application site. If a dry mix method of application is used, water is added at the application nozzle to create a wet mix for spraying. Inhalation will not be a major source of exposure once water has been added, however, dermal exposure may be frequent and prolonged, and accidental ocular contact may occur.

There will be frequent worker contact with cured concrete and mortar containing the notified substance, however, it will be part of an inert matrix, and will not be bioavailable.

7. PUBLIC EXPOSURE

There will be negligible public exposure from transport, storage, reformulation, application and disposal. The notified substance and reformulated cement will not be sold to the public and will only be available for use in industry. Release of dust may occur during blending and use, but good workplace practices would limit dust dispersion to adjacent public areas. Accidental dry cement spills during storage, transport, blending, use or transport will be sprayed with water and allowed to cure before being disposed of to landfill. Residual wet cement will be cured prior to disposal in the same manner.

The public may come into contact with the notified substance in the form of cured cement, but the cured cement will be in a solid mass and the components of the cement are unlikely to be released to the environment or absorbed through biological membranes.

8. ENVIRONMENTAL EXPOSURE

Release

The material will be blended with Portland cement at Sika facilities and repacked into 25 kg bags. Although there is some release of dust during the process of opening the bags of product and transferring them to the blender, this dust is collected in filters attached to an exhaust system. The dust is eventually removed from the filter bags, mixed with water and allowed to set prior to disposing into landfill.

Some release is likely during use. However, this will invariably set into a solid mass through reactions with water. This solid is likely to be collected with rubble and other construction waste and disposed of into landfill.

The notifier provided the following estimates for annual release of the material:

Activity	***Annual release (kg)***
leaking/damaged bags	250
blending	750
application	2 000
clean up of equipment and disposal of residuals	4 000
TOTAL	7 000

Once incorporated into building masonry the material will be stable and would be unlikely to degrade even under harsh environmental conditions.

Fate

All the material will eventually set into a solid matrix and will be placed into landfill or possibly used for backfill on other construction sites. The cement minerals

would be subject to very slow weathering and degradation processes, and may eventually be converted to clay-type minerals.

9. EVALUATION OF TOXICOLOGICAL DATA

Variation has been requested for toxicological data relating to the notified substance. The notifier states that there is no information available on the toxicity of SikaSet AU and has presented a summary of information available on Portland cement as proposed analogue data. It is accepted that the health hazards are expected to be similar to those of Portland cement. A chemical comparison of SikaSet AU and Portland cement is provided in Section 2 of the Assessment Report. The notifier states that crystalline silica is present in SikaSet AU at concentrations of less than 1%. The chromium content of SikaSet AU is 80 ppm total chromium, and 2 ppm hexavalent chromium.

9.1 Acute Toxicity

Summary of the acute toxicity of Portland Cement

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	N/A	not available	N/A
acute dermal toxicity	N/A	not available	N/A
skin irritation	human	irritant	(4, 5, 6)
eye irritation	N/A	not available	(5)
skin sensitisation	human	sensitiser	(5, 7)

9.1.1 Oral Toxicity

No animal or human data regarding the acute oral toxicity of SikaSet AU or Portland cement are available. The notifier states that it would be impractical to carry out acute oral toxicity studies with these cement products. The notifier also states that the cement phase compounds are high molecular weight, inorganic components, which are unlikely to be absorbed across biological membranes. Any effects due to ingestion of cement products are likely to be local corrosion or irritation of the gastro-intestinal tract, due to the high pH (> 11.0) of these substances.

9.1.2 Dermal Toxicity

No animal or human data are available on the acute dermal toxicity of the notified substance or analogue substances. The notifier states that the inorganic phase compounds are unlikely to be absorbed across the skin, however, absorption of impurities such as hexavalent chromium is possible. In addition, the corrosive nature of the notified substance would preclude acute animal dermal exposures.

The dermal toxicity of the notified substance will be largely an effect of the alkalinity of the cement products.

9.1.3 Inhalation Toxicity

Variation has been requested for this toxicological endpoint, as there are no animal or human data available for acute inhalation toxicity of SikaSet AU or Portland Cement. Effects in acute inhalation studies would be expected to be related to the corrosive nature of cement when it reacts with water, and 'nuisance dust' effects at high airborne concentrations. There have been a number of studies carried out with animals and humans following repeat inhalation exposures (see Section 9.2).

9.1.4 Intraperitoneal Toxicity

As part of the documentation for the exposure standard for Portland cement (8), the ACGIH reviewed a study where Portland cement dust was administered by intraperitoneal injection to guinea pigs. An absorptive reaction, resulting in peritoneal nodules was reported. These progressively reduced in size and resolved spontaneously. The ACGIH reported that ingested dusts that exhibit this type of response are considered to be potentially harmless.

9.1.5 Skin Irritation

There are no animal data available for either the notified substance or Portland cement for skin irritation. However, there is extensive literature indicating that severe skin irritation and burns have been observed in people handling both dry and wet Portland cement (4, 5, 6). The pH of wet Portland cement is typically 12.5 - 13.0, and the pH of wet SikaSet AU is slightly lower at approximately 11.0. This alkalinity is largely due to the presence of calcium oxide, which reacts with water to form calcium hydroxide. The pH of the notified substance (when wet) is only 0.5 pH units under the threshold for materials that have predictable corrosive potential, and hence do not require testing under the OECD acute dermal irritation/corrosion guideline (9).

Based on information available from human exposures, Portland cement would be considered a moderate to severe irritant to human skin. Given the pH of SikaSet AU when wet (approximately 11.0), it is likely that it will also be a moderate to severe skin irritant in humans.

9.1.6 Eye Irritation

There is no animal eye irritation data available for the notified substance or Portland cement. An increased incidence of conjunctivitis and 'foreign body' in the eyes of Portland cement factory workers directly exposed to cement dust has been reported, when compared with cement factory workers whose jobs did not involved direct exposure to cement dust (5).

The skin irritation/corrosion potential of Portland cement and the high pH of wet SikaSet AU indicates that the notified substance would be likely to cause moderate-severe eye irritation.

9.1.7 Skin Sensitisation

There is no information from animal studies carried out with Portland cement regarding skin sensitisation potential. Evidence with humans, however, indicates that the hexavalent chromium content of this substance can induce cement dermatitis in some workers (5, 7). Hexavalent chromium is also an impurity in SikaSet AU, present at concentrations of approximately 2 ppm (total chromium content of 80 ppm).

Based on the chromium content, Portland cement would be regarded as a skin sensitiser in humans. As SikaSet AU has a similar hexavalent chromium content, it is predicted that a similar sensitisation potential will be evident.

9.2 Repeated Dose Toxicity

Two repeat-dose inhalation studies with Portland cement in rats have been reviewed by the HSE (5). In one study, groups of animals were exposed to cement dust at concentrations of 86 - 548 $mg.m^{-3}$ for 6 hours per day, 6 days per week for periods ranging from 1 week to 12 months. Inflammation and damage in the tracheal and bronchial epithelium and alveolar fibrosis and emphysema were observed. The second study involved caged rats which were placed in a continuously operating cement plant, where the 'mean dust level' was 80 $mg.m^{-3}$, for 2-4 months. Inflammation and/or atrophy of the mucous membrane of the nose and pharynx was observed .

There has been extensive documentation of the effects of human exposure to Portland cement dust (5). According to this HSE review, a number of studies carried out on cement workers had inadequate control groups, and did not adjust for factors such as age and smoking habits. Due to the limitations of many of these studies, the 'tentative' conclusions drawn from these studies indicate that exposure to cement dust has probably been related to rhinitis and an increase in chronic productive cough, and may have caused slight abnormalities, as detected by chest radiography. The ACGIH (8) reached a similar conclusion, indicating that Portland cement is considered a 'nuisance' dust that does not cause fibrosis and has little potential to induce adverse effects on the lung.

A study reviewed by the HSE (5) examined 2 736 cement workers from Portland cement plants, and compared them to 755 workers in non-cement industry plants. Atmospheric monitoring indicated that airborne cement concentrations ranged from 0.01 - 78.6 $mg.m^{-3}$ (geometric mean 2.90 $mg.m^{-3}$) total dust (0.57 $mg.m^{-3}$ (geometric mean) respirable dust). Workers completed a questionnaire on respiratory symptoms, and spirometric tests were performed on a large proportion of subjects. After adjustment for age, sex, height, race and smoking habits, the authors found that there were no significant differences between the findings respiratory function for the two study groups.
The HSE concluded in their review that respiratory effects have been recorded with Portland cement where conditions have been very dusty, and that no significant effects have been observed in several studies (such as the one summarised

above), where atmospheric concentrations have been maintained at under 7.8 $mg.m^{-3}$ total dust and 2.2 $mg.m^{-3}$ respirable dust.

9.3 Genotoxicity/Carcinogenicity

No data are available for either the notified substance or Portland cement. The genotoxic potential of cement will be determined on the basis of levels of the impurity hexavalent chromium (5), which is a well documented genotoxin/animal carcinogen (10).

The HSE review examined evidence relating to the potential carcinogenicity of Portland cement, and concluded that the position with relation to carcinogenicity remains uncertain. They indicated that there was no convincing evidence for any increased incidence of any site-specific cancer resulting from exposure to Portland cement dust, but also acknowledged that the results available were not consistently negative.

9.4 Overall Assessment of Toxicological Data

There is no toxicity data available for single oral, dermal or inhalational exposure to the notified substance or an analogue substance, Portland cement. This is accepted on the basis of the impracticalities of carrying out acute dermal and oral studies with a very alkaline substance. The lack of acute inhalation data is accepted on the basis of the availability of epidemiological data collected from Portland cement factory workers repeatedly exposed to cement dust.

As the notified substance is alkaline when wet (pH of approximately 11), SikaSet AU is likely to be a severe skin and eye irritant. Analogue data from workers handling Portland cement products shows that skin irritation and burns have been reported in workers exposed to wet cement products. The hexavalent chromium content of Portland cement products can produce sensitisation reactions in susceptible workers. While the addition of ferrous sulfate will limit the amount of hexavalent chromium in SikaSet AU, a sensitisation response may occur in some workers.

Damage to the respiratory tract was found in rats exposed to high levels of Portland cement dust for periods of 1 week to 12 months. Epidemiological studies carried out with workers in Portland cement factories produced evidence for respiratory effects such as rhinitis and an increase in chronic productive cough, and slight lung abnormalities. It was concluded that conditions where these effects had been recorded were very dusty, and that no significant effects have been observed in several studies where atmospheric concentrations have been maintained at lower levels. Similar effects are expected with the notified substance, due to the similarity of the chemical composition of Portland cement and the notified substance.

The genotoxic and carcinogenic potential of Portland cement products are equivocal, and are related to the hexavalent chromium content of the cement.

Based on the information summarised above, SikaSet AU would be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (1) in relation to skin and eye irritant effects. The levels of hexavalent chromium present as an impurity in the cement could also potentially cause skin sensitisation and weak genotoxic effects.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The major component minerals in the notified material have no inherent chemical toxicity and consequently pose no hazard to aquatic organisms. Although the material contains significant amounts of chromium, most of this is in the trivalent state and is unlikely to pose any threat to the environment. Furthermore, exposure to water or moisture will set the material into a solid mass effectively locking up the contained chromium.

The physical nature of the material, primarily its fine particulate nature, may cause problems if released in quantity to the water compartment. This could be expected to cause murkiness, although this would clear in time as the particles settle and join the bottom sediments. If high concentrations (greater than 100 $mg.L^{-1}$) of solids were to be present in natural waters as a result of release, then behavioural aberrations and possibly death in fish could result due to interference with gill function. In confined water bodies, the pH would rise as a result of hydrolytic reactions of the water with the reactive surface of the particles.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

When used in the manner indicated by the notifier, the environmental hazard from the notified substance is very small.

Any release of the material as a powder would be transitory, since on exposure to moisture it would set into a solid mass. Release into the water compartment may cause a transitory physical hazard, particularly to fish in the case of substantial release to confined water bodies or slowly flowing streams. Most of the material will be used in building applications where it would pose no hazard to the environment.

Waste material would be placed into landfill where degradation to clay type minerals is expected to be extremely slow.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The occupational health risk to waterside, warehouse and transport workers is expected to be negligible, as they will be handling unopened 25 kg bags of the notified substance.

There is a moderate health risk for workers who may be exposed to the notified substance during blending operations. Dermal, inhalation and ocular exposure is possible when workers are handling the notified substance in powdered, pure form. Exposure to powdered concrete/mortar products containing up to 33% of the notified substance may also occur during packaging, cleaning and maintenance operations. There is also a moderate health risk for workers applying cement and mortar products containing the substance at up to 33%. These workers are likely to be handling the products in both wet an dry form.

Given the alkalinity of the notified substance and similar cement products when they are wet, moderate to severe eye and skin irritation is likely to occur if exposure occurs. The chromium content of the notified substance may also cause skin sensitisation in susceptible individuals. If workers are operating in very dusty conditions, lung effects may occur following repeated exposure (see above discussion in Section 9.2). However approximately half of the particles are under the size considered to be respirable. Given these particle sizes and the results of HSE and ACGIH reviews (see Section 9.2), airborne dust levels of the notified substance should be kept to a minimum. Workers should be aware that occupational exposure standards (3) have been set for a number of components and impurities in SikaSet AU (see notifier's Material Safety Data Sheet (MSDS) for details).

The notified substance will not be sold to the public and will only be available for use in industry. There will be negligible public exposure from transport, storage, reformulation, application and disposal. The general public may come into contact with cured cement made with the notified substance. However, the cement will be in a solid mass and the components of the cement are unlikely to be released to the environment or absorbed through biological membranes.

Based on the information provided and the intended use, the notified substance does not appear to represent a significant risk to public health.

13. RECOMMENDATIONS

To minimise occupational exposure to SikaSet AU the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (11) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (12);
- Industrial clothing should conform to the specifications detailed in AS 2919 (13);
- Impermeable gloves or mittens should conform to AS 2161 (14);
- All occupational footwear should conform to AS/NZS 2210 (15);

- If engineering controls and work practices are not sufficient to reduce inhalation exposure to a safe level, a mask which conforms to Australian/New Zealand Standard 1715-1994: *Use and Maintenance of Respiratory Protective Devices* and Australian/New Zealand Standard 1716-1991: *Respiratory Protective Devices* should be worn;

- Spillage of the notified substance should be avoided, spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;

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

- A copy of the MSDS should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified substance was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (16).

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

2. National Occupational Health and Safety Commission 1994, *Control of Workplace Hazardous Substances [NOHSC:1005(1994), 2007(1994)]*, Australian Government Publishing Service, Canberra.

3. National Occupational Health and Safety Commission 1995, 'Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment, [NOHSC:1003(1995)]', in *Exposure Standards for Atmospheric Contaminants in the Occupational Environment: Guidance Note and National Exposure Standards*, Australian Government Publishing Service, Canberra.

4. Kelsey, R. & Alvey, T. 1995, 'Skin Burns from Prolonged Exposure to Wet Cement', *Journal of the Americal Podiatric Medical Association*, vol. 85, no. 6, pp. 315-317.

5. Health and Safety Executive 1993, *Portland Cement Dust - Criteria Document for an Occupational Exposure Limit*, Health and Safety Executive, United Kingdom.

6. Skiendzielewski, J. 1980, 'Cement Burns', *Ann. Emerg. Med.*, vol. 9, no. 6, pp. 316-8.

7. Avnstorp, C. 1991, 'Risk Factors for Cement Eczema', *Contact Dermatitis*, vol. 25, pp. 81-88.

8. American Conference of Government Industrial Hygienists 1991, 'Portland Cement', in *Documentation of the Threshold Limit Values and Biological Exposure Indicies*, ACGIH, Ohio.

9. Organisation for Economic Co-operation and Development 1995-1996, *OECD Guidelines for the Testing of Chemicals on CD-Rom*, OECD, Paris.

10. American Conference of Government Industrial Hygienists 1991, 'Chromium', in *Documentation of the Threshold Limit Values and Biological Exposure Indicies*, ACGIH, Ohio.

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

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

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

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

15. Standards Australia/Standards New Zealand 1994, *Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear*, Standards Association of Australia/Standards Association of New Zealand, Sydney/Wellington.

16. National Occupational Health and Safety Commission 1994, *National Code of Practice for the Preparation of Material Safety Data Sheets[NOHSC:1008(1994)],* Australian Government Publishing Service, Canberra.