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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Notified Chemical in Sikadur 349

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**Notified Chemical in Sikadur 349****1. APPLICANT**

Sika Australia Pty Ltd of 55 Elizabeth Street WETHERILL PARK 2164 has submitted a standard notification statement in support of their application for an assessment certificate for 'Notified Chemical in Sikadur 349'.

2. IDENTITY OF THE CHEMICAL

Chemical Name: cyclohexanemethanamine, 5-amino-1,3,3-trimethyl-, adduct with 2,2'-[(1-methylethylidene) bis (4,1-phenyleneoxymethylene)] bis [oxirane]

Chemical Abstracts Service (CAS) Registry No.: 106107-74-8

Other Names: bisphenol A diglycidyl ether isophorone diamine copolymer

Sikadur 349 (contains < 20% of the notified chemical)

Trade Name: Sikafloor-92/93 B New Top Coat Hardener (synonymous with Sikadur 349)

Molecular Formula: $(C_{21}H_{24}O_4.C_{10}H_{22}N_2)_x$

Molecular Weight: 681 (lowest molecular weight species); the molecular weight could not be determined by conventional means; in the manufacturing process, the bisphenol A diglycidyl ether is added gradually to a large excess of isophorone diamine so that the number-average molecular weight (NAMW) is probably below 1 000 and more likely to be toward 681

**Method of Detection
and Determination:**

infrared spectroscopy

3. PHYSICAL AND CHEMICAL PROPERTIES

The notified chemical is synthesised *in situ* and is not isolated. Therefore, the only physico-chemical properties available are for the product Sikadur 349.

**Appearance at 20°C
and 101.3 kPa:**

straw coloured liquid with amine-like odour

Boiling Point:

> 205°C (based on benzyl alcohol having the lowest b.p.)

Specific Gravity:

1.03 at 20°C

Vapour Pressure:

based on that for benzyl alcohol: 0.02 kPa at 25°C

Water Solubility:

see comments below

**Partition Co-efficient
(n-octanol/water):**

see comments below

**Hydrolysis as a Function
of pH:**

see comments below

Adsorption/Desorption:

see comments below

Dissociation Constant:

pK_a approximately 11: see comments below

Flash Point:

> 94°C (based on benzyl alcohol)

Autoignition Temperature:

436°C (based on benzyl alcohol)

Comments on Physico-Chemical Properties

No water solubility data were provided with the notification, although the notifier states that the presence of a hydrophobic moiety in the adduct would detract from significant aqueous solubility. The presence of this group would not confer affinity for water on the adduct, but it is noted that the material also contains several primary and secondary amino groups which would be protonated, and hence positively charged (see further below) in the usual environmental pH region (pH between 4 and 9). This will favour water solubility, and consequently the possibility that the notified adduct is significantly soluble should not be discounted. The notifier correctly points out that the other components of the Sika Hardener SD 349 formulation will be appreciably soluble in water. The adduct contains no linkages which will be susceptible to hydrolytic degradation in the usual environmental pH region.

No partition coefficient data were provided with the original notification which is acceptable since the adduct is a complex mixture of species, some of which may have amphoteric properties, and consequently determination of log P_{ow} would be a difficult task. However, the notifier stated that the presence of the hydrophobic moiety in the adduct molecules would give a high octanol/water partition coefficient. As discussed above the adduct also contains primary and secondary amine groups which will be protonated and positively charged (see below) in the usual environmental pH region (pH between 4 and 9), and this will strongly favour partitioning into the water phase. It is considered that in the usual environmental pH region, the adduct will partition into the aqueous phase. Subsequent information provided by the notifier, including some calculated estimates of log P_{ow} (log P_{ow} between negative 3.3 and 2.4 estimated using recognised computer programs, and assuming various degrees of amino group protonation) supports this view, and therefore the material should be highly water soluble in the environment.

Under usual environmental conditions the notified adduct is unlikely to associate with the organic component of soils and sediments (due to the expected low value of P_{ow}), but since the adduct molecules carry positive charges, it is probable that they will be adsorbed onto the negatively charged surfaces of silicate minerals and bound through electrostatic interactions.

The primary and secondary amino groups in the adduct species will have pK_a of between 10 and 11, and consequently under the usual environmental pH conditions where the pH is between 4 and 9, these will be protonated and confer positive charge on the molecules.

4. PURITY OF THE CHEMICAL

The notified chemical is synthesised *in situ* with bisphenol A diglycidyl ether being added to solvent in the reactor vessel followed by an excess of isophorone diamine (IPD). When the reaction is complete and the reaction mix cooled, other components are added to produce the formulation described in section 5 below. Thus, the purity of the notified chemical is not determined except that the level of bisphenol A diglycidyl ether was shown to be undetectable by high performance liquid chromatography.

5. USE, VOLUME AND FORMULATION

The notified chemical is a low molecular weight polymer formed through condensation of IPD with bisphenol A diglycidyl ether. An excess of isophorone diamine is present, and on completion of the reaction there is an approximately 1:1 weight ratio of adduct to IPD. This reaction mixture contains less than 20% adduct and < 20% IPD, with the remainder made up of solvents and other reactive amines.

The notified chemical is a component of a hardener used in a 3-pack epoxy coating for floors. Less than 5 tonnes per year is expected to be manufactured in the first five years.

6. OCCUPATIONAL EXPOSURE

The notified chemical will be manufactured at the notifier's site in a 2 000 L mixing vessel fitted with a mechanical stirrer and water cooling jacket. The raw materials are pumped from their storage containers into the mixing vessel via an automated dosing system. The mixing operation is conducted under local and general ventilation. A number of hazardous ingredients are added to the reactor vessel comprising the individual components and various additions once the reaction is complete. The nature of the hazardous ingredients make it necessary for workers to wear a suitable respirator, eye and hand protection and protective clothing. Exposure to the notified chemical will be minimised as a result.

The contents of the reactor vessel are transferred by hose to a filling machine which is within an enclosed chamber and filling is conducted under local and general ventilation. Thus, worker exposure to the notified chemical should be low. Following filling of the final formulation into 2.8 kg metal cans, they are packed into cardboard boxes for distribution.

Cleaning of equipment will be carried using a suitable solvent which will be collected and disposed of to a liquid waste facility by a licensed contractor. Some exposure to the notified chemical is possible during these operations although the likely concentration of chemical in the solvent is not known precisely.

Applicators will open the contents of part B (Hardener SD 349) and add it to a pre-mixed combination of part A (epoxy resin) and pigment. The mixture is stirred with an electric stirrer for 2 to 3 minutes. Part C (quartz sand) is then added and the mixture blended to homogeneity. The mixture, which has a pot life of 15 to 30 minutes, is applied to the floor with a notched trowel or spreader. After this further spreading or texturing may be done with a roller. The majority of the curing process is complete with 12 hours and full curing takes about one week. Equipment is recommended to be cleaned using a small amount of Sika Colma Cleaner. Potentially dermal and ocular exposure to the notified chemical is high.

7. PUBLIC EXPOSURE

There is negligible potential for public exposure to the notified chemical during manufacturing operations, transport or use.

Manufacturing operations will occur in a bunded area under local and general ventilation, with the filling machine housed within an enclosed chamber. Equipment will be cleaned with solvent, which will be disposed of to a liquid waste facility by a licensed contractor. Given the containment and procedures described, public exposure to this material is exceedingly improbable.

The notified chemical is expected to be poorly soluble in water is likely to adsorb strongly to organic matter. The likelihood of public exposure from a transport accident is very low providing measures described in the Material Safety Data Sheet (MSDS) for cleaning up spills are followed.

Negligible public exposure is expected from use of the notified chemical in floor coatings either during mixing, application or disposal of waste. The public is likely to make contact with floor coatings containing the notified chemical, but by this stage the notified chemical will be in the form of a cross-linked component within a hardened, inert substrate, from which it could not be absorbed.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier anticipates that around 43.5 kg of the notified chemical will be released annually as a result of manufacturing activities. Of this, 34 kg is expected from spills and leaks, while the remaining 9.5 kg will result from cleaning of the manufacturing equipment. Spillage and leaks of material will be contained within bunded areas at the site of manufacture, and treated with other waste solutions and solvents in the treatment plant at the Sika facility. It is expected that most of the notified adduct will become associated with the waste sludge, and will then be disposed of into landfill or be incinerated. The notifier indicates that disposal of such residues is undertaken by a waste removal contractor.

The production equipment is cleaned using a high boiling point hydrocarbon solvent (solvesso 150) in a semi-automatic process. The notifier indicates that the spent solvent is recovered after the cleaning process, and is periodically collected by a waste contractor for solvent recycling. It is assumed that residuals of the notified material contained within the waste solvent are recovered into waste sludge, and are either incinerated or placed into landfill. In using the product as a hardening agent for epoxy floor coatings, it is expected that 210 kg of the notified adduct will be released per year as a consequence of leaks and spills (55 kg), cleaning application equipment (75 kg) and residuals left in containers (80 kg). The spilt material is allowed to cure and solidify before being disposed of into landfill, and similarly the residual material of parts A and B of the surfacing formulation are combined in the tins, allowed to cure and disposed of to landfill.

It is likely that under conditions of normal use on industrial floors some of the cured surface material will be abraded and become associated with dust etc. This material would most likely be picked up by vacuum cleaners and hence deposited into landfill with cleaning waste, and some may enter storm water/sewage systems as a consequence of hosing out industrial premises.

At the end of their useful life the concrete floors would be broken up and the residue placed into landfill, or possibly be used as clean backfill in new construction. In either case the notified material will be contained within a highly crosslinked polymer matrix and will be immobile.

Fate

Material disposed of into landfill will be incorporated in a solid polymer matrix where it will be immobilised. The polymer will be very slowly degraded through the biological and abiotic processes operative in landfills, and will degrade to relatively harmless gases such as methane, ammonia, and carbon dioxide. A similar fate is predicted for the cured material associated with old broken concrete used as backfill. Any uncured material released as a result of accidents is likely to become protonated in the environment due to the high content of primary and secondary amino groups, and this will confer high water solubility on the released material. However, it is likely that the positive charges will enable adsorption onto negatively charged ion exchange sites on soil and clay particles, and consequently the material would become associated with sediments and be slowly broken down by natural biological and abiotic processes. Similarly, it is likely that any particles of cured material (eg from abraded dust etc) released into stormwater or sewage systems would deposit into sediments, and be slowly destroyed through these processes.

No data on biodegradation specific to the new material accompanied the notification, but the notifier indicated that non-cyclic amines are not readily biodegradable, and persist in the environment. In the absence of other data, it must be assumed that the notified material would behave in a similar fashion, and would not be readily biodegradable. However, most organic material is degraded eventually through the agency of biological and abiotic processes, and it could be expected that the new compound would be degraded in an aerobic environment to water, and oxides of carbon and nitrogen, while in an anaerobic situation the products would likely be water, methane and ammonia.

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicological data for the notified chemical are not available. The notifier proposes that the primary and secondary amine functionalities on IPD will largely determine the toxicological profile of the notified chemical and suggests also that it would be indicated by toxicity data for alkylamines in general. Data on IPD were submitted as this is a component of the notified chemical and is present in the manufactured reaction product. Data on m-xylylene diamine (m-XDA), diethylenetriamine (DETA) and triethylene triamine (TETA) were submitted to build up a general toxicological profile for alkylamines commonly used as epoxy adduct hardeners.

9.1 Summary of the acute toxicity of IPD, m-XDA, DETA and TETA

<i>Test</i>	<i>Species</i>	<i>Outcome</i>	<i>Reference</i>
acute oral toxicity	rat	LD ₅₀ : 660 or 930 mg.kg ⁻¹ (m-XDA)	(1)
		1 080 mg.kg ⁻¹ (DETA)	(1)
		2 500 mg.kg ⁻¹ (TETA)	(2)
acute dermal toxicity	rabbit	LD ₅₀ : 2 000 mg.kg ⁻¹ (m-XDA)	(1)
		1 090 mg.kg ⁻¹ (DETA)	(1)
		805 mg.kg ⁻¹ (TETA)	(2)
acute inhalation toxicity	rat	LC ₅₀ = 3.75 mg.L ⁻¹ (1 hour) (m-XDA); equivalent to 4 hour LC ₅₀ of 1.9 mg.L ⁻¹ ; ocular irritation, lacrimation and dyspnoea observed; lung, liver and kidney macroscopic changes	(1)
		DETA: no mortality after 8 hour exposure to 300 ppm	(1)
skin irritation	guinea pig	corrosive (m-XDA)	(1)
	rabbit	severe irritant (m-XDA at 10% and 50%)	(1)
		severe irritant (DETA)	(2)
		severe irritant (TETA)	(2)
eye irritation	rabbit	irritant (m-XDA)	(1)
		severe irritant (DETA)	(2)
		severe irritant (TETA)	(2)
skin sensitisation	human	skin sensitiser: IPD	(3, 4)
		m-XDA,	(1)
		DETA	(1)
		TETA	(5)
		respiratory sensitiser: DETA	(1)

9.2 Repeat Dose Toxicity - 90-Day Feeding Study (6)

A 90-day repeat dose toxicity study of TETA, a medical chelating agent, in the drinking water of rats and mice was conducted to identify and characterise possible toxic effects and to evaluate their relationship to the effect of TETA on

circulating copper levels. Three different diets were used, a standard cereal-based diet, a purified diet and a purified copper-deficient diet.

Fisher 344 rats (18/sex/group) were given TETA in drinking water at doses calculated to be 10, 55 or 276 mg.kg⁻¹.dy⁻¹ in males and 14, 70 or 352 mg.kg⁻¹.dy⁻¹ in females for up to 92 days. TETA administration resulted in liver copper depletion at all dose levels in rats fed the purified diet and in high dose rats fed the cereal-based diet. Generally, the copper depletion was inadequate to induce overt signs of copper deficiency. However, there was an indication of copper deficiency in high dose rats fed the purified diet. The lowest level of TETA causing any effect in rats that probably was not related to its effect on copper levels was the high dose. The response noted at this level (uterine dilatation) was not considered to be of major toxicological importance.

B6C3F1 mice (20/sex/group) received TETA in drinking water at doses calculated to be 17 to 22, 92 to 107 or 443 to 551 mg.kg⁻¹.dy⁻¹ for 92 days. Signs of TETA toxicity at the high dose were observed in animals fed the purified diet. These signs were inflammation of the lung interstitium, haematopoietic cell proliferation of the spleen, liver periportal fatty infiltration, kidney weight reduction, reduced renal cytoplasmic vacuolisation, and body weight gain reduction. These signs do not appear to be related to copper deficiency. Neither the low copper diet nor TETA had significant effects on plasma levels of Cu, Zn or Fe.

9.3 Genetic Toxicity (7)

The potential for genotoxicity among the alkylamines appears to be variable according to a study of six alkylamines in a battery of tests. DETA was found not to be mutagenic in *Salmonella typhimurium* or Chinese Hamster ovary (CHO) cells and did not induce sister chromatid exchange (SCE) or unscheduled DNA synthesis (UDS). m-XDA did not induce micronuclei in mouse bone marrow cells or chromosomal aberrations in CHO cells. TETA did not induce micronuclei in mouse bone marrow cells or gene mutation in CHO cells. However, TETA was mutagenic in *Salmonella typhimurium*, caused an increase in SCE in CHO cells and increased UDS in rat hepatocytes. Two other alkylamines (tetraethylene pentamine and aminoethylpiperazine) had weak mutagenic potential.

9.4 Overall Assessment of Toxicological Data

Alkylamines, as exemplified by m-XDA, DETA, TETA and IPD, appear to be of moderate acute toxicity via the oral, dermal and inhalational routes. They appear to be moderate to severe skin irritants, severe eye irritants and may be corrosive to both skin and eye. Alkylamines appear to be both skin and respiratory sensitisers.

In a 90-day repeat dose feeding study using TETA, a medical chelating agent used to treat the effects of excess copper in humans, organ toxicity (lung, liver, kidney, spleen) was observed in mice at a dose of approximately 500 mg.kg⁻¹.dy⁻¹. These effects were not related to copper deficiency. Although liver copper levels were reduced in rats, this did not lead to signs

of copper deficiency.

The genotoxicity of alkylamines appears to be variable. A report by Leung (7) comparing a series of 6 related alkylamines concluded that mutagenic activity may be associated with the higher amines. There appeared to be a lack of mutagenic activity *in vivo* which were said to correlate with negative results in animal cancer bioassays for cutaneous treatment with ethylenediamine, DETA and TETA.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No tests were carried out on the toxicity of the compound to aquatic organisms, and instead the notifier provided some data estimated from a computer model based on Structure Activity Relationships (SAR's) for isophorone diamine. This compound is one of the principal reactants used in manufacturing the notified chemical, and its molecular structure is substantially preserved in the reaction product. Consequently the notifier considered the ecotoxicity properties of IPD to be at least as severe as the notified material. The model employed in calculated the ecotoxicological estimates for IPD was "ECOSAR" developed by the United States EPA.

ESTIMATED ECOTOXICITY DATA FOR ISOPHORONE DIAMINE

<i>Test</i>	<i>Species</i>	<i>Results</i>
Acute Toxicity	Fish (no species specified)	LC ₅₀ (96 h) = 47 mg.L ⁻¹
Acute Immobilisation	<i>Daphnia magna</i>	LC ₅₀ (48 h) = 3.5 mg.L ⁻¹
Growth Inhibition	Algae (no species specified)	EC ₅₀ (96 h) = 6.5 mg.L ⁻¹

While the calculated data indicate that isophorone diamine is likely to be at least moderately toxic to aquatic organisms, the model employed will depend very strongly on the value of log P_{ow} and pH put into the model, and these were not detailed in the information provided by the notifier. However, while these results are of interest in respect of the model compound isophorone diamine, analogies with the notified material are problematic. Given the lack of quantitative data, and uncertainties associated with the important parameters used in the ECOSAR model, it appears that the notified material should be regarded as potentially highly toxic to aquatic species.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified chemical is expected to be low when it is manufactured and used in the indicated manner. Although the material is likely to be highly toxic to aquatic organisms if released into the environment alone, this is likely only in the case of serious accident. Most release to the environment will be in association with an epoxy resin as part of a semi solid highly crosslinked mass which will immobilise the toxic material. Released material is expected to be placed into landfill, where very slow degradation processes will be operative and will decompose the material to water and the usual landfill gases such as ammonia, methane and carbon dioxide.

If any of the un-crosslinked material were to enter the water compartment, its inherent potential toxicity is likely to be mitigated through assimilation into sediments, where it would be expected to slowly degrade through the agency of bacteriological and abiotic processes.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

In the absence of toxicological data for the notified chemical, it has been accepted that the toxicological profile will be indicated by its amine functionalities. Data for a number of alkylamines were considered. On this basis the notified chemical would be expected to exhibit moderate acute toxicity via oral, dermal and inhalational routes. However, the predicted minimum molecular weight of 681 suggests that absorption of the molecule across biological membranes would be slow. Therefore the acute toxicity of the notified chemical would be expected to be somewhat lower than for the other alkylamines. In addition, the higher molecular weight should correlate with a low vapour pressure and consequently low acute inhalation toxicity.

In general, the data summarised in section 9 suggest that alkylamines can be considered severe skin and eye irritants with the possibility of being corrosive. A similar conclusion should be drawn for the notified chemical in the absence of other information. On a similar basis, the notified chemical should be considered a skin sensitiser but may not be a respiratory sensitiser due to its expected low vapour pressure.

The notified chemical should be considered potentially genotoxic on the basis that some alkylamines exhibit genotoxicity and it is not possible to conclusively rule it out on structural grounds.

Taking all the components into account, Sikadur 349 would be classified as hazardous according to the NOHSC's *Approved Criteria for Classifying Hazardous Substances* (8) in terms of corrosivity, skin and respiratory sensitisation and acute lethal effects.

During manufacture of the notified chemical and filling into small (2.8 kg) metal drums workers are potentially exposed to hazardous amines and bisphenol A diglycidyl ether. As a result, good local and general ventilation is employed at the notifier's site, and the site is bunded to contain spills and the filling machine is in an enclosed chamber. Also, due to the hazards of the reactants, workers are required to wear respirators, hand and eye protection and protective clothing despite engineering controls. Use of this personal protective equipment would serve to minimise exposure to the notified chemical.

Full personal protective equipment is also required to be worn during cleaning of equipment with solvent. The solvent is stated to be collected and disposed of to a liquid waste facility by a licensed contractor. Exposure of workers to the notified chemical will be minimised by the use of personal protective equipment.

Other than alkylamines, the Sikadur 349 also contains benzyl alcohol at a concentration above the cut-off at which the mixture should be considered harmful by inhalation and if swallowed according to NOHSC's *List of Designated Hazardous Substances* (9).

During mixing of Sikadur 349 with other components and spreading the mixture on floors, there is a risk of severe skin and eye irritation with possible corrosivity, a risk of skin and respiratory sensitisation and a risk of acute lethal effects. Thus, protective clothing and footwear and respiratory, skin and eye protection as described below should be worn.

Under normal conditions of use the public are not expected to come into contact with the notified chemical in its uncured form so that the risk of adverse health effects is considered to be negligible. In the cured floor coating containing the notified chemical it is not bioavailable so, again, the public health risk is negligible.

13. RECOMMENDATIONS

To minimise occupational exposure to the notified chemical the following guidelines and precautions should be observed:

During manufacture of Sikadur 349, in addition to good local and general ventilation and isolation of filling operations, the following personal protective equipment should be worn. Similar personal protective equipment should be worn during mixing and use of the product:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (10) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (11);
- Respiratory protection should conform to AS/NZS 1715 (12) and 1716 (12);
- Industrial clothing should conform to the specifications detailed in AS 2919 (13) and AS 3765.1 (14);

- Impermeable gloves or mittens should conform to AS 2161 (15);
- All occupational footwear should conform to AS/NZS 2210 (16);
- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal after donning the above personal protective equipment;
- 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 Hardener containing the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (17).

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

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17. 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.