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June 2001

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

ADK STAB NA-11

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FULL PUBLIC REPORT**ADK STAB NA-11****1. APPLICANT**

Nissho Iwai Australia Limited of Level 17, Gateway 1 Macquarie Place Sydney 2000 has submitted a limited notification statement in support of their application for an assessment certificate for ADK STAB NA-11. No claim was made for exempt information.

2. IDENTITY OF THE CHEMICAL

Chemical Name: 12H-dibenzo[d,g][1,3,2]dioxaphosphocin,2,4,8,10-tetrakis(1,1-dimethylethyl)-6-hydroxy-6-oxide, sodium salt

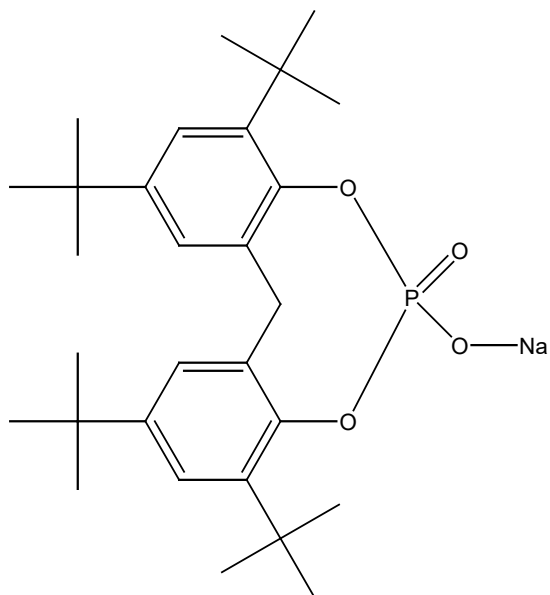
Chemical Abstracts Service (CAS) Registry No.: 85209-91-2

Other Names: ADK STAB NA-11
2,2'-Methylenebis(4,6-di-tert-butylphenol) phosphate sodium salt
ADK Stab NA 11UY
Mark NA 11
Mark NA 11UF
Sodium 2,2'-methylenebis(4,6-di-tert-butylphenyl) phosphate

Marketing Name: ADK STAB NA-11

Molecular Formula: $C_{29}H_{43}O_4P.Na$

Structural Formula:



Molecular Weight: 509.62

Weight Percentage of Ingredients: 100 %

Method of Detection and Determination: IR Spectrum

Spectral Data: IR shifts were observed at 2957, 2868, 1390 and 1362 (*t*-butyl groups), 1600, 896 and 787 (aromatic CH stretches) and 1098 cm⁻¹ (O-P=O(O)).

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa: White odourless powder

Boiling Point: Melting not observed; reaction or decomposition observed above 313-334 °C

Density 1180 kg/m³

Vapour Pressure: 0.11 x 10⁻³ kPa at 20°C

Water Solubility: 1850 mg/L at 19.5°C

Partition Co-efficient (n-octanol/water): log P_{ow} > 6.2 at 21.5 °C +/- 0.5 and at pH 1 (see comments below).

Hydrolysis as a Function of pH: Conducted: 2.4 hours and 5 days:

at pH 4.0	no reading	no reading
at pH 7.0	100.9	89.2
at pH 9.0	103.6	72.4

$t_{1/2}$ (25 °C) > 1 year (see comments below).

Particle size:	Mean = 16 µm; median = 19.3 µm; mode = 80.6 µm. Approx. 25 % of particles in respirable range (<10 µm), > 90 % of particles in inspirable range (<100 µm) [NOTOX project 288168].
Adsorption/Desorption:	Immobile (see comments below).
Dissociation Constant:	Could not be determined experimentally as the due to water solubility was too low (see comments below).
Flash Point:	Not applicable. Notified chemical is a solid.
Flammability Limits:	Not provided. The notified chemical is described as not highly flammable or pyrophoric. It is combustible. [NOTOX projects 288179, 288181, 288192]
Autoignition Temperature:	360 °C [NOTOX project 288203]
Explosive Properties:	Not explosive [NOTOX project 288214]
Reactivity/Stability:	The notified chemical is stated to be chemically stable. The notified chemical has no oxidising properties in accordance with EC Directive 92/69, Method A.17.

3.1 Comments on Physico-Chemical Properties

Full test results were provided. The melting point test was conducted using the method outlined in OECD TG 102 using a differential scanning calorimeter (Notox, 2000a).

The density was determined using a gas comparison pycnometer according to OECD TG 109 (Notox 2000b).

The vapour pressure was measured with a capacitance manometer using OECD TG 104 (Notox 2000c). The chemical was found to be moderately volatile (Mensink 1995).

The water solubility test was conducted using the flask method of OECD TG 105 and HPLC (Notox 2000d). The moderate water solubility reflects the salt form.

Hydrolysis as a function of pH was measured using the HPLC method outlined in EEC Directive 92/69/EEC, Annex V, Part CX, Method C7 (Notox 2000e). At pH 7 and 9 a decrease in concentration of <10 % was observed after 5 days at 50 °C and it was concluded that the test chemical is hydrolytically stable at these pH. At pH 4 it was not possible to

determine the hydrolysis rate as the solution had to be diluted because of interference of the buffer and consequently the concentrations were at the limit of detection.

The partition coefficient of the notified chemical was measured using the HPLC method of OECD TG 117 at pH 1 (Notox 2000f). This pH was used to conform to the OECD and EEC guideline that the Pow be determined at a pH at least one unit above the pKa for a basic group (of which the test chemical has none) and one unit below the pKa for an acidic group (the organic part of the chemical has a pKa of 2.10). The result indicates a very high log Pow (>6.2) but log Pow would be expected to be much lower at the higher environmental pH range of 4-9 when the acid functionality is not protonated as illustrated by the water solubility. The partition coefficient was also calculated as a quotient of the *n*-octanol solubility and the water solubility and was 6.9 (log Pow = 0.8 at 20 °C and pH 7.5).

The adsorption of the notified chemical was studied using three soils: Cranfield 115 (2.8 % organic matter, clay loam, pH 8.1), Cranfield 164 (3.4 % OM, silt loam, pH 7.2) and Cranfield 230 (1.4 % OM, sandy loam, pH 5.1), according to OECD TG 106 (Notox 2000g). Results are summarised in the following table.

<i>Soil</i>	<i>K_d (cm³/g)</i>	<i>K_{om} (cm³/g)</i>	<i>K_{oc} (cm³/g)</i>	<i>% adsorbed.</i>	<i>% desorbed</i>
Cranfield 115	25.1	908	1566	80	<24
Cranfield 164	16.2	469	808	74	33
Cranfield 230	37.4	2710	4671	86	<23

The notified chemical is considered immobile in the soils tested (Mensink 1995). The high values for Koc indicate that the chemical would be strongly bound to the sediments and soils.

The dissociation constant could not be measured experimentally at the water solubility of the notified chemical. However calculations were performed using pKalc version 3.2 (module in PALLAS version 2.1) software and the pKa value for the acidic functionality in the structure was estimated to be 2.10.

4. PURITY OF THE CHEMICAL

Degree of Purity: 100 %

Hazardous Impurities: None.

5. USE, VOLUME AND FORMULATION

The notified chemical is used as a UV stabiliser in the production of polypropylene products such as automotive moulded parts for the interior/exterior of motor vehicles and components of electrical appliances. The notified chemical will be formulated into plasticised pellets in

Australia. The final production of plastic articles is either conducted at the formulation site or at a customer site.

The estimated import volume of the notified chemical is 0.9 tonne/yr in each of the first five years. The notified chemical is imported in 15 kg plastic bags as the neat chemical in powder form. Plastic products will contain a final concentration of up to 0.5 % ADK STAB NA-11.

6. OCCUPATIONAL EXPOSURE

The following categories and number of workers may be exposed to the notified chemical during importation, reformulation and plastic article production.

Waterside, Transport and Storage Workers (up to 2-5 workers)

The notified chemical will be transported 15 kg plastic bags by road directly to the customer site. It is anticipated that waterside workers, transport drivers and warehouse workers would only be exposed to the notified chemical if the packaging was breached.

Production Plant Operators (9-15 workers, 2 hours/day, 80 days/year)

The production of pelletised plastic involves the manual transfer of ADK STAB NA-11 to a charger, where it is weighed and added to plastic powder, filler and other additives. The mixture is then dropped into a mixer to blend the ingredients and formed into pellets and moulded into the final product. The main point of exposure to the notified chemical will occur when the plant operators manually open the bags containing the neat chemical powder and pour it into the charger or mixer. The notified chemical has a mean particulate size deeming it 'highly inspirable' (mean 16 micrometer, median 19 micrometer) with *ca.* 25 % of particles in the respirable range. Mixers, which receive the raw materials, have local exhaust ventilation to dust filter bags. While loading the mixers, which are fitted with doors, the workers wear a half-face respirator, safety glasses, overalls and a head covering. There is a 24-hour ventilation system in operation and the product is stored in an area that meets the requirements covered in the MSDS on fire and explosion.

Potential dust exposure is also likely when the plant operators change the filter bags on the dust extraction system of the two mixers. This typically occurs on a weekly basis. The MSDS states that the product can form an explosive dust/air mixture.

Skin contact with the notified chemical may occur following extrusion of the powder mix into its encapsulated form as pellets or as the pellets are shovelled into the hopper for article production. However, in both cases, the notified chemical is in its encapsulated form (at a concentration of up to 0.5 %). Based on previous usage of ADK STAB NA-11, blooming of the notified chemical to the external surface of the extruded article is not anticipated.

Laboratory Technician (1 hour/day, 80 days/year)

A laboratory technician will collect up to 3 samples per five tonne batch by scooping the required amount of raw material (product containing the notified chemical) into a sample container and carry out routine laboratory analysis. Protective clothing including a laboratory coat, safety glasses and gloves will be worn by the laboratory technician while handling the raw material.

7. PUBLIC EXPOSURE

The notified chemical will not be sold to the public. However, exposure of the general public to the notified chemical may occur in the event of an accidental spill during transport. According to the MSDS provided for ADK STAB NA-11, a large spill should be incinerated or placed in a suitable container for disposal by a contractor and a small spill should be mopped, wiped or soaked up immediately. Disposal should be in accordance with local, state or national legislation.

Plastics, containing up to 0.5% of notified chemical, will be used in the interior and exterior of motor vehicles. Since the notified chemical will be incorporated into the final plastic product, the risk of exposure of the public to the notified polymer is considered low.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Release of the notified chemical during the pelleting process is expected to be of low volume and to landfill or incineration. Minimal release is expected from spills, equipment start-up and shut-down and dust extraction filter bags and all the waste will be disposed to landfill after collection into a dumpmaster bin on site. The notifier anticipates that waste chemical be released as residues remaining in the import bags after 'emptying' to be up to 1 % or < 9 kg/annum and presumably the empty bags will be disposed to landfill with the rest of the waste.

Very little release of the chemical is anticipated during use of the formulated pellets in the preparation of the extruded plastic products. The notifier's "worst-case" estimate is a total of up to 4% of the import volume (< 36 kg/annum) being disposed to landfill as waste from the reformulation and extruding processes.

Articles containing the notified chemical are likely to have a wide distribution throughout the community, indicating that long term release of the chemical (eg as result of discarding old electrical equipment and car parts) would be very diffuse.

Potential release of the chemical may occur as a result of blooming from the manufactured articles during day to day use. This process is the slow diffusion of the chemical from the interior of the plastic article to the surface, where it may be removed through cleaning processes and released in waste water (presumably mainly to sewer). However, release through this route is expected to be diffuse and at very low levels. The notifier indicates that the chemical is bound within the matrix of the polymer and that blooming has not been reported during manufacture or by customers.

Recycling of the plastic in discarded articles is theoretically possible, but is not anticipated to take place on a large scale. Consequently, the majority of the imported chemical will be discarded with old plastic articles at the end of their useful lives, and these are likely to be either incinerated or be placed into landfill.

8.2 Fate

Although little of the notified chemical is likely to be released during formulation and article manufacture processes, any that is released is likely to be placed into landfill or incinerated.

The eventual fate of the majority of the imported chemical will be strongly linked to that of discarded plastic articles, and likely placed into landfill or incinerated.

Material disposed of into landfill will be incorporated and immobilised in a solid polymer matrix (*ie* the plastic article). However, the polymer matrix will be slowly degraded through the biological and abiotic processes operative in landfills, and this would release the notified chemical. Diffusion of the polymer to the surface of broken pieces of plastic by blooming could contribute to this mode of release.

The compound has a high experimentally determined Koc (Log Koc 2.9-3.7) indicating strong affinity for the organic component of soils and sediments and low mobility in these media. The chemical when bound to, or otherwise associated with soils and sediments, could be expected to slowly degrade through the agency of biological and abiotic processes operative within landfills.

Complete combustion of the chemical in the presence of excess oxygen would be expected to destroy the material with production of water vapour and oxides of carbon. Some solid phosphate salts would also be formed, and these would become incorporated with the waste incinerator ash. There is a possibility that phosphorus pentoxide may be generated during incineration, depending on the degree of thermal decomposition. However, the gas components from combustion should be treated with alkali-water and activated sludge before release, which should prevent release of toxic gases to the environment.

The high value for log Pow (> 6.2) indicates some potential for bioaccumulation (Connell, 1989). However, the moderate water solubility (1.85 g/L), low and diffuse release volumes, and the fact that the chemical is unlikely to enter the water compartment mitigate the risks associated with bioaccumulation.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of ADK STAB NA-11

<i>Test</i>	<i>Species</i>	<i>Outcome</i>	<i>Reference</i>
acute oral toxicity	mice	no acute oral toxicity	Japan Environmental Sanitation Centre, Dept of Environmental Biology (unvalidated study)
acute dermal toxicity	rat	non-irritating	HLA Study No 90801944, Hazelton Laboratories America, Inc., 1990
skin irritation	rabbit	non-irritating	HLA Study No 90801944, Hazelton Laboratories

eye irritation	rabbit	slightly irritating	America, Inc., 1990. HLA Study No 90801945, Hazelton Laboratories America, Inc., 1990.
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9.1.1 Oral Toxicity (Japan Environmental Sanitation Centre, Dept of Environmental Biology, undated)

<i>Species/strain:</i>	mice
<i>Number/sex of animals:</i>	50 males
<i>Observation period:</i>	10 days post treatment
<i>Method of administration:</i>	Oral, via olive oil
<i>Test method:</i>	No reference to guidelines. Five groups of ten males were treated at five dose levels (2731, 3550, 4615, 6000 and 7800 mg/kg bw) and the LD ₅₀ is >7800 mg/kg bw.mg/kg) of the notified chemical.
<i>Mortality:</i>	No deaths were reported for the study.
<i>Clinical observations:</i>	Individual body weights were shown not to have any significant increase during the study.
<i>Morphological findings:</i>	No data was provided.
<i>Comment:</i>	This report does not comply with GLP practices.
<i>LD₅₀:</i>	> 7800 mg/kg
<i>Result:</i>	Within the confines of an unvalidated study, the notified chemical is of very low acute oral toxicity in mice.

9.1.2 Skin Irritation (Primary Dermal Irritation Study of Mark NA-11 in Rabbits, HLA Study No 90801944, Hazelton Laboratories America, Inc., 1990)

<i>Species/strain:</i>	New Zealand White albino rabbits
<i>Number/sex of animals:</i>	3 per sex
<i>Observation period:</i>	72 hours
<i>Method of administration:</i>	0.5 g in 0.9 % saline applied to intact skin; semi occlusive dressing

Test method: USEPA GLP Standards, 40 CFR 792 (1983)

Comment: No dermal reactions were observed as a result of the treatment using the notified chemical. No signs of irritation were observed in any of the animals, *i.e.* all Draize scoring was given as 0.

Result: the notified chemical was non-irritating to the skin of rabbits

9.1.2 Eye Irritation (Primary Eye Irritation Study of Mark NA-11 in Rabbits, HLA Study No 90801945, Hazelton Laboratories America, Inc., 1990)

Species/strain: New Zealand White albino rabbits

Number/sex of animals: 3 per sex

Observation period: 21 days

Method of administration: 0.03 g (0.1 mL equivalent)

Test method: According to EPA Guideline 81-4.

Draize scores of unirrigated eyes:

Animal	Time after instillation											
	1 day		2 days		3 days		4 days		7 days			
Cornea	<i>o</i>	<i>a</i>	<i>o</i>	<i>a</i>	<i>o</i>	<i>a</i>	<i>o</i>	<i>a</i>	<i>o</i>	<i>a</i>		
1	0 ¹	0	0	0	0	0						
2	0	0	0	0	0	0						
3	0	0	0	0	0	0						
4	0	0	0	0	0	0						
5	0	0	0	0	0	0						
6	0	0	0	0	0	0						
Iris												
1		0		0		0						
2		0		0		0						
3		0		0		0						
4		1		1		0						
5		1		0		0						
6		0		0		0						
Conjunctiva	<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	2	1	1	1	0	0	0	0	0			

2	2	1	0	2	0	0	0	0	0
3	2	1	1	2	0	0	0	0	0
4	2	1	0	2	0	0	0	0	0
5	2	1	0	2	0	1	0	0	0
6	2	1	0	2	0	0	0	0	0

¹ see Attachment 1 for Draize scales

o = opacity a = area r = redness c = chemosis d = discharge

Irrigated eyes: The average primary eye irritation scores for 24 hours, 2 days and 3 days are 8.3, 4.8 and 0, respectively.

Comment: The notified chemical produced iridal involvement and moderate irritation (blanching and a clear discharge) of the conjunctivae was seen in five animals at 24 hours post treatment. Although sodium fluorescein treatment was used, the preinitiation time was not recorded, hence no results can be concluded from the staining. All ocular irritation cleared within 72 hours after instillation of the notified chemical.

Result: the notified chemical was slightly irritating to the eyes of rabbits.

9.2 Genotoxicity

9.2.1 *Salmonella typhimurium* Reverse Mutation Assay (*Salmonella typhimurium* Reverse Mutation Assay with ADKSTAB NA-11, Cytotest Cell Research GmbH & Co., Project 205211, F.R.G. 1991).

Strains: *S. typhimurium* strains: TA98, TA100, TA1535, TA1537

Metabolic activation: Rat liver S9 fraction from animals pretreated with Aroclor 1254

Concentration range: 10, 33, 100, 333, 1000 and 5000 µg/plate. Positive controls used were 4-Nitro-o-phenylene-diamine, sodium azide, 2-aminoanthracene.

Test method: OECD TG 471

Comment: Toxicity was observed at the higher doses levels +/- S9 in all strains used. There was no significant or reproducible increase of the revertant colonies as compared to the solvent control.

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

9.2.2 Chromosomal Aberration Assay in Chinese Hamster V79 Cells (Chromosomal Aberration Assay in Chinese Hamster V79 Cells *In Vitro*, Cytotest Cell Research GmbH & Co., Project 205233, F.R.G. 1991).

Cells: Female Chinese Hamster V79 cells

Metabolic activation system: Rat liver S9 fraction from animals pretreated with Aroclor 1254

Test method: OECD TG 473

Dosing schedule:

Metabolic Activation	Experiment Number	Test concentration (µg/mL)	Controls
-S9	1	treatment times;	Positive: EMS
		7 hours; 1.5 µg/mL 18 hours; 0.1; 1.0; 2.0 µg/mL 28 hours; 2.0 µg/mL	Negative: Sodium carboxymethyl-cellulose
+S9	2	7 hours; 4.0 µg/mL 18 hours; 0.4; 4.0; 8.0 µg/mL 28 hours; 8.0 µg/mL	Positive: CP Negative: Sodium carboxymethyl-cellulose <i>Solvent control: ethanol</i>

EMS - ethyl methanesulphonate

CP - cyclophosphamide

Test method: OECD TG 476

Comment: There was no significant increase in cells with structural aberrations after treatment with the test chemical at any fixation interval either +/- S9 (0 - 3. % as cf. control 0.5 – 2.0 %) No relevant deviation in the occurrence of polyploid metaphases was observed as cf. control. The test substance was toxic at ≥ 10 µg/mL and 3 µg/mL with and without S9, respectively. Therefore, the doses used in the main assay were lower than normally used.

Result: The notified chemical was non clastogenic and did not induce structural chromosomal aberrations under the conditions of the test.

9.2.3 Gene Mutation Assay in Chinese Hamster V79 Cells (Gene Mutation Assay in Chinese Hamster V79 Cells *In Vitro* with ADK STAB NA-11, Cytotest Cell Research GmbH & Co., Project 205222, F.R.G. 1991).

Cells: Female Chinese Hamster V79 cells

Metabolic activation system: Rat liver S9 fraction from animals pretreated with Aroclor 1254

Dosing schedule:

Metabolic Activation	Experiment/ Study Number	Test concentration (µg/mL)	Controls
-S9	1	0.03, 0.1, 0.3, 1.0, 2.0 and 3.0 µg/mL	Positive: EMS Negative: Sodium carboxymethyl-cellulose
+S9	2	0.1, 0.3, 1.0, 2.0, 3.0, 6.0 and 10 µg/mL	Positive: 7,12-dimethylbenz(a)anthracene in DMSO Solvent control: DMSO

EMS - ethyl methanesulphonate

CP - cyclophosphamide

DMSO - dimethylsulfoxide

Test method: OECD TG 476

Comment: The study was carried out in two independent experiments. In both experiments, treatment at the highest concentration reduced the plating efficiency of the cells. In Exp 1, several doses (1 µg/mL -S9 and 6 µg/mL + S9) were not utilised due to high cytotoxicity. In Exp 2, an unexpected low cytotoxicity was observed (- S9) as *cf.* to Exp 1 and pre-experimental results. Doses of 2.0 and 3.0 µg/mL induced a decrease in plating efficiency; these were however, used to evaluate a mutagenic change.

The mutation rates overall were not found to have increased (biologically) relevant as *cf.* negative and solvent controls. The notified chemical did not significantly induce a reproducible concentration-dependent increase in colony numbers (0 to 65.8 mutant/10⁶ cells) which were in the range of the negative control numbers (6.6 to 43.7 mutants/10⁶ cells).

Result: The notified chemical did not significantly induce point mutations at the HGPRT locus in V79 cells, hence was not mutagenic under the conditions of the test.

9.3 Overall Assessment of Toxicological Data

The notified chemical has low acute oral toxicity ($LD_{50} > 7800$ mg/kg bw, unvalidated). It is not a skin irritant, but is a eye slight irritant, which is characterised by iridal irritation (score = 1) and conjunctival redness, chemosis and discharge (score = 1-3). The notified chemical (10-5000 microgram/plate) was not mutagenic in an Ames Test performed in *Salmonella typhimurium* strains (TA98, TA100, TA1535, TA1537 and TA1538), with and without metabolic activation. In Chinese Hamster V79 cells, the notified chemical did not induce point mutations at the HGPRT locus (0.03-3 microgram /mL with S9 and 0.1-10 microgram /mL without S9) and did not cause chromosomal aberrations in the presence (0.1-2 microgram /mL) and absence (0.4-8 microgram /mL) of metabolic activation.

Based on the toxicological data provided the notified chemical would not be classified as a a hazardous substance under the *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified chemical is not expected to be high when it is used for the manufacture of electrical appliances and motor vehicle parts as indicated in the notification.

Very little of the notified chemical is expected to be released during manufacture and article processes. The notifier estimates that this release would be 45 kg/annum at the maximum import volume of 0.9 tonnes (5 %). However, some slow release of the chemical may occur as a result everyday use and cleaning of the polymer articles, and this release is likely to enter the sewer system with discarded cleaning water. In the sewer the compound will become strongly associated with sediments.

Plastic articles containing the notified chemical, such as household appliances or automotive parts are likely to be discarded at the end of their useful lives and not recycled. The discarded articles are most is likely to be placed into landfill or incinerated.

If placed into landfill, the notified chemical is likely to be slowly released as a consequence of the slow degradation of the polymer matrix. Once released in this manner it is expected to become associated with the organic component of soils and sediments. The chemical is not expected to be readily biodegradable. However, once released and adsorbed to soils and sediments in a landfill, it is expected to slowly degrade through the biological and abiotic processes operative in these situations.

Very little of the compound is expected to enter the water compartment so exposure to aquatic organisms is expected to be low. The notified chemical is not expected to be readily biodegradable and the high value for log Pow and moderate water solubility indicate some potential for bioaccumulation. However, any potential for bioaccumulation will be mitigated by the expected low exposure to the water compartment and the moderate molecular weight (510 g mol⁻¹).

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment

The notified chemical was of very low acute oral toxicity in mice and non-irritating to the skin of rabbits. It was slightly irritating to the eyes of rabbits. All genotoxic studies yielded negative findings, including the *Salmonella typhimurium* Ames test and the Chromosomal Aberration Assay in Chinese Hamster V79 cells. The notified chemical did not significantly induce point mutations at the HGPRT locus in the V79 cells.

Based on the toxicological data provided the notified chemical would not be classified as a hazardous substance under the *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999).

The notified chemical is imported in powder form, with *ca.* 25 % of particles in the respirable range (<10 micrometer) and < 90 % in the inspirable range (<100 micrometer).

Occupational Health and Safety

Worker exposure to the powder may occur whilst weighing and manually loading the notified chemical and mixture into the moulding machine. The notified chemical is 'highly inspirable'. In the event of contact, dermal exposure via the dermal, ocular and inhalational routes are possible. Potential dust exposure is also likely when the plant operators change the filter bags on the dust extraction system of the two mixers, typically on a weekly basis. Workers are reported to wear half-face respirators, safety glasses, overalls and a head covering during the weighing and manually loading procedures.

The mixers which receive the raw materials have local exhaust ventilation to dust filter bags and workers wear PPE, in the form of chemical resistant gloves, protective clothing, dust masks and safety goggles. While loading the mixers, which are fitted with doors, the workers wear a half-face respirator, safety glasses, overalls and a head covering. The notifier states that possible phosphorus pentoxide emission may occur during the incineration process. The MSDS states that the product can form an explosive dust/air mixture, thus appropriate grounding, venting and explosion provisions should be in place. There is a 24-hour ventilation system in operation and the product is stored in an area that meets the requirements covered in the MSDS on fire and explosion.

Other contact with the notified chemical will occur following extrusion of the product into its encapsulated form, either as pellets or as the final product at a concentration of up to 0.5 %. Worker exposure and absorption of the notified chemical from pellets and articles is expected to be negligible. The notifier states that blooming from articles has not been reported.

The notified chemical is a slight eye irritant. There is risk of inhalational irritation with the intake of the fine powder (NOHSC nuisance dust exposure standard for inspirable dust (10 mg/m³ TWA)). The ACGIH exposure standard for insoluble particulates in respirable fractions of 3 mg/m³ TWA should be adhered to in the workplace thereby reducing the possible adverse health effects as a result of exposure.

Given these considerations, the chemical should not pose a significant health risk in the occupational environment.

Public Health

The notified chemical is not available for sale to the public and will be used as a component of automotive plastics. Since the notified chemical will be incorporated into the final plastic product, the risk of public health exposure of the public to the notified chemical is considered to be low.

13. RECOMMENDATIONS

To minimise occupational exposure to **ADK STAB NA-11**, the following guidelines and precautions should be observed:

- The generation of dust clouds should be prevented to avoid the risk of inhalation and fire. Appropriate respiratory devices should conform to AS 1337; head covering should be utilised where appropriate for protection against hazardous chemicals AS3765.1-1990;
- Storage of the chemical; the notified chemical should be kept in a dry container (S7), tightly closed (S8), and in a well-ventilated place (S9). Avoid contact with peroxide, oxidising agents and general acid (S14);
- Respiratory protection should be used where respirable dust is not monitored below the ACGIH exposure standard (3 mg/m³ TWA);
- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992) industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.2 (Standards Australia, 1990) impermeable gloves or mittens should conform to AS 2161 (Standards Australia/Standards New Zealand, 1998); all occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);
- Spillage of the notified chemical should be avoided. Spillages should be swept up promptly and put into containers for disposal;
- A copy of the MSDS should be easily accessible to employees.

If products containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1994).

workplace practices and control procedures consistent with State and Territory hazardous substances regulations must be in operation.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1999).

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, the director must be informed if any of the circumstances stipulated under subsection 64(2) of the Act arise, and secondary notification of the notified chemical may be required. No other specific conditions are prescribed.

16. REFERENCES

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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		

CONJUNCTIVAE

<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

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