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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

LONZABAC 12.30

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

LONZABAC 12.30

1. APPLICANT

International Chemicals Pty Ltd, Simcock Avenue, Spotswood, Victoria, 3015.

2. IDENTITY OF THE CHEMICAL

Chemical name:	N-3-Aminopropyl-N-dodecyl-1,3-propanediamine,
Chemical Abstracts Service (CAS) Registry No.:	2372-82-9
Other names:	N,N-Bis(3-aminopropyl) dodecylamine; Di-3-aminopropyl laurylamine;
Trade names:	Lonzabac 12.100 (100% active) Lonzabac 12.30 (30% active) Throughout this report "Lonzabac 12" is used to refer to the active component without implying concentration.
Molecular formula:	$C_{18}H_{41}N_3$
Structural formula:	$C_{12}H_{25}N\ (CH_2CH_2CH_2NH_2)_2$
Molecular weight:	299

Methods of detection and determination:

NMR, Infrared Spectroscopy, Colourimetric Analytical Procedure, Thin Layer Chromotagraphy and Gas Chromotography.

Spectral data:

IR Spectrum major absorption peaks at 720, 820, 1100, 1300, 1380, 1470, 1580, 1600, 2860, 2930, 3280, 3340 cm^{-1}

Proton NMR and carbon 13 NMR were provided.

3. PHYSICAL AND CHEMICAL PROPERTIES

The physical and chemical properties listed below correspond to the pure substance unless otherwise indicated.

Appearance at 20°C and 101.3 kPa: Colourless to slightly yellow clear liquid.

Odour:	fishy
Boiling Point:	155-160°C
Density:	870 kg/m^3
Vapour Pressure (predicted):	1.33 x 10^{-4} kPa at 25°C from homologue data
Water Solubility:	>300 g/l (30% active)
Partition Co-efficient (n-octanol/water) log P_{OW}:	Not determined
Hydrolysis as a function of pH:	Not determined
Adsorption/Desorption:	Not determined
Dissociation Constant:	Not determined
Flash Point:	Not determined
Reactivity/Stability:	Incompatible with aldehydes, nitrosating agents, concentrated strong acids and hypochlorite.

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· **comments on physico-chemical data**

The boiling point provided is that of undiluted Lonzabac 12.100, using OECD guideline TG 103.

The vapour pressure for Lonzabac 12.100 (the pure form) was calculated using homolog data. An estimated boiling point for Lonzabac 12.100 @ 6 mm Hg is about 275°C. The corresponding vapour pressure/temperature curve (semilog) for Lonzabac 12.100 therefore predicts a vapour pressure at atmospheric pressure and 25°C to be 10^{-3} mm Hg.

The degree of hydrolysis at 25°C under a range of pH conditions has not been tested. An examination of the structure reveals no recognisable hydrolysable groups, and the company submits that hydrolysis is not expected under normal environmental conditions.

The partition co-efficient was not measured for Lonzabac 12.30 or 12.100, on the grounds that available test methods are not applicable to surfactants. The company has included literature support for this omission, which is acceptable.

Adsorption/desorption and dissociation constant testing were not conducted. The substance, containing 1 tertiary and 2 primary amine groups, will have basicity typical of these functionalities. In addition, the high solubility of the substance would limit the applicability of testing procedures for these properties. In the biodegradability sludge dispersion test (see below) between 1.5 and 6.5% adsorbed to sludge, indicative of poor adsorption potential. Therefore the omission of these data is acceptable.

The company detailed conditions that may promote physical instability and performance deterioration of the chemical under normal use conditions. These included mixing with acids of any kind (which will lead to salt formation and thus a lessened efficiency as a lubricant) and mixture with bacterial contamination (which will lead to biodegradation and loss of foaming/surfactant properties). Lonzabac 12.30 has no oxidising properties.

Finally, the company states that it has not determined the specific decomposition products and their associated hazards for Lonzabac 12.30. During incineration, the formation of acrylonitrile may be

expected, but final products of decomposition are expected to be water, carbon dioxide and nitrous oxides.

4. PURITY OF THE CHEMICAL

Degree of purity:	100% (distilled)
Toxic or hazardous impurities:	None
Non-hazardous impurities: (> 1% by weight)**:**	None
Additive/Adjuvant:	Lonzabac 12.30 contains 70% water.

5. INDUSTRIAL USE

Lonzabac will be imported into Australia in 200 L steel containers as either the pure distilled substance Lonzabac 12.100 or as Lonzabac 12.30 containing 30% of the pure substance. The projected imported volume of the notified chemical is 5-10 tonnes in the first year and 10-50 tonnes per annum in the next four years.

Lonzabac 12.30 be used as metal lubricant/corrosion inhibitors in gear chain applications in the food and beverage industry in Australia.

The company estimates that approximately 20 sites will use the chemical as a lubricant. These sites will be primarily located in both Melbourne and Sydney (although other customers are expected), and are all associated with the food processing industry. The notifier predicts that each plant will use approximately 2.5 tonnes per year of the notified substance.

Lubricant will be applied to gearing by either spray or dipping. Use in trays may also occur following the recycling of lubricant, prior to disposal when spent. Spent lubricant will be discharged to on-site treatment plants.

6. OCCUPATIONAL EXPOSURE

Exposure of workers to the notified chemical may occur during formulation of the chemical with soaps and surfactants or during the use of the resulting lubricant. Personnel involved in shipping, storage and in transfer of material to a blending tank at the start of the formulation process may be exposed to 100% active substance. 2-3 workers at the formulation site will be exposed to (Lonzabac 12) 0.1-10% active substance during transfer and cleaning equipment.

Application of the notified polymer is by dipping articles into or spraying articles with the formulation. Exposure of workers may occur via accidental contact or during maintenance of equipment. The product will be recycled through the application system until the content of the notified chemical is 'spent' by bacterial degradation or other means.

7. PUBLIC EXPOSURE

Since Lonzabac 12.100 is to be imported and used only in commercial processing plants, with negligible waste discharge, the public is unlikely to be exposed to the chemical.

8. ENVIRONMENTAL EXPOSURE

. Release

· Formulation

Lonzabac 12.30 will form 0.1 to 10% of formulated lubricants. At present there is only one company known to be planning to formulate the chemical. This factory is located in Melbourne, and is licensed with the Victorian EPA. The plant is claimed to have tertiary treatment facilities for all waste products. International Chemical Pty. Ltd intends to sell the product to formulators for blending with soaps and surfactants to manufacture lubricants/corrosion inhibitors of process equipment, especially gearing.

Emptied containers of Lonzabac 12.30 following formulation form a minor source of release. The company estimates that approximately 10 mL of Lonzabac 12.30 will remain in containers after formulation. These residues are minor and will be disposed of in washings when the containers are sent to drum recyclers. No significant release is expected from this source.

The major release of Lonzabac 12.30 is expected to occur when treated waste water is released from the tertiary treatment plants of users' plants. Such effluents will then pass to publicly owned treatment works.

Another possible form of release is from accidental spills during transport to customers. As the drums used to transport Lonzabac 12.30 are quite large, accidental spillage could result in significant contamination of waterways, sewers etc. The company recommends the use of adsorbent materials to soak up any spills that may result either from transport accidents or rupture of drums, and stresses the need to prevent Lonzabac 12.30 entering waterways without treatment.

· Disposal

Disposal of small quantities of unused Lonzabac (container residues and spillages) is expected to be by incineration. It is emphasised by the company that no direct release of Lonzabac to sewers or watercourses should be allowed, and adsorption of the substance onto PIG "socks" or "hot hogs" is recommended for containing spills and clean-up operations.

Disposal of washing and spent material will be to on-site treatment plants as outlined above. Waste water will be retained in treatment ponds until released to the sewage system.

. Fate

The spent aqueous gear chain formulation is discharged to on-site waste water processing. The notifier indicates that, based on European experience, food and beverage manufacturers are likely to have on-site waste treatment ponds which handle wastewater with high BOD/COD characterisation. This treatment process would be expected to assist in the biodegradation of remaining Lonzabac before discharge to the sewerage system.

Previous EPA discussions with Sydney and Melbourne Water Boards indicate that Australian food and beverage manufacturers must have on-site waste treatment plants which adhere to strict effluent release guidelines and/or have a user-pay system with levies based on volumes of effluent and levels of contaminants in the effluent, respectively (1,2). However, on-site plants vary from primary (which use filtration and flotation to remove suspended material and solids) to tertiary (water "polishing" ponds).

· Biodegradation

The biodegradation of Lonzabac 12.30 was determined according to a modified OECD Confirmatory Test Method 303A. This test determined the biodegradability of the test material under conditions which simulate treatment in an activated sludge plant. The method, as outlined in the OECD

Guidelines determines the amount of ultimate biodegradability by measurement of dissolved organic carbon or the chemical oxygen demand. In this case, a "substance specific" Disulfinblue active substance (DSBAS) was used to determine the amount of primary degradation in the case of the notified substance.

Lonzabac-12 was fed to the test unit with the inlet and outlet concentration and quantities adsorbed on sludge monitored throughout the 25 day study duration. The substance found at the outlet and adsorbed to sludge was considered to be biologically undegraded Lonzabac.

The primary biological degradability from the 12 th day of the test was calculated to reach an average of 96% (indicating rapid primary degradation), with between 1.5 and 6.5% adsorption to the sludge over a 36 day period. This adsorption was reversible, with some of the adsorbed material desorbed and then biodegraded.

It is unknown how far the biodegradation proceeded, as literature data (3), indicate that tertiary amines carrying bulky substituents are not easily degradable. Therefore it is unlikely that the mean figure of 96% reflects the ultimate biodegradation potential of Lonzabac. Rather, the 96% degradation reflects levels of primary biodegradation that may be achieved during water treatment.

- **Bioaccumulation**

The notifier considers bioaccumulation unlikely given the high water solubility and high biodegradation potential. This is acceptable.

The high water solubility will ensure that Lonzabac 12.30 will disperse rapidly in the aquatic compartment if accidental spillage, for example, occurs. The chemical should biodegrade in natural surface water, and is not expected to readily adsorb to sediments. Lonzabac 12.30 is therefore not expected to persist in the environment for a significant period.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Table 1Summary of the acute toxicity of Lonzabac 12

Test	Species	Outcome	Ref
oral toxicity	rat	LD_{50} 280 mg/kg (males) LD_{50} 245mg/kg (females)	(4)
dermal toxicity	rat	LD_{50} > 600mg/kg	(6)
skin irritation	rabbit	severely irritating/ corrosive	(8)
skin sensitisation	guinea pig	non-sensitising	(10)

9.1.1 Oral Toxicity (4)

These studies were carried out according to OECD Guidelines for Testing of Chemicals No.: 401 (5).

In a range-finding study, single doses of 5000, 3000, 2000, 1000 and 500 mg/kg bodyweight of P4150 were administered by gavage to 5 groups of Sprague-Dawley rats (1/sex). Animals were observed for mortality for 14 days. Both animals in the 5000, 3000 and 2000 mg/kg dose groups died on day one. One animal in the 1000 mg/kg dose group died on day 5.

In the main study, a single dose of 2000, 1000, 500 or 250 mg/kg P4150 was administered by gavage to four groups of 10 rats (5/sex). The animals were observed 1 and 4 hours after dosing and once

daily for 14 days. Bodyweights were recorded on the day 1, 7, 14, and at death. All surviving animals were killed on day 14. Necropsy was performed on all animals.

Seven animals in the 1000 mg/kg and all ten animals in the 2000 mg/kg dose group died, 24 hours after dosing. Clinical signs and symptoms observed in all animals were hunched posture, piloerection, lethargy and slowed respiration after administration. Animals receiving 1000 or 2000 mg/kg had increased salivation one hour after dosing. Weight gain in survivng animals were depressed during the first week and appeared normal during the second week of the study, with the exception of one male in the 1000 mg/kg dose group.

Necropsy findings in all dead animals were abnormally red lungs, dark livers and kidneys, haemorrhage of the gastric mucosa and congestion of the small and large intestine.

The oral LD_{50} of P4150 (Lonzabac 12.30) was 933 mg/kg in males and 812 mg/kg in females. These corresponds to an LD_{50} for the pure chemical of 280 mg/kg in males and 245 mg/kg in females.

9.1.2 Dermal Toxicity (6)

These studies were carried out according to OECD Guidelines for Testing of Chemicals No.: 402 (7).

A single dose of ~ 2 ml/kg (corresponding to 2000 mg/kg P4150) was applied by occlusive application to an area of clipped skin corresponding to approximately 10% of the body surface of Sprague Dawley rats (5/sex) for 24 hours. Animals were observed for 14 days.

No deaths were recorded during the study. All animals had hunched posture, piloerection, and lethargy on day 1. One animal had red brown staining around the eyes. All application sites had large scales which persisted to the end of the study. Body weight gains were decreased during week 1. All animals showed normal weight gains in week 2.

The LD_{50} was found to be >2000 mg/kg P4150, corresponding to >600 mg/kg of the pure notified chemical.

9.1.4 Skin Irritation (8)

These studies were carried out according to OECD Guidelines for Testing of Chemicals No.: 404 (9).

A single dose of 0.5 ml of P4150 containing 30% active material was applied by occlusive application to the clipped flank of six New Zealand White rabbits for four hours. The Site of application was examined approximately 1, 24, 48 and 72 hours and 7 days after removal of the dressing. Skin reactions were assessed according to Draize.

All treated sites showed severe erythema (redness) and moderate to severe oedema (swelling). Scales formed on the application site were still present when the study was terminated 7 days later. Oedema decreased over the time of the observation period.

The notified chemical was considered to be a severely irritant and corrosive to the skin of rabbit.

9.1.5 Eye Irritation

There is no requirement for eye irritation studies on a substance known to be severely irritating to the skin.

9.1.6 Skin Sensitisation (10)

These studies were carried out according to OECD Guidelines for Testing of Chemicals No.: 406 (11).

After a preliminary experiment in which 1.6% P4150 in distilled water was found to be the highest tested non-irritant concentration, the concentrations of 1% was chosen for induction and 0.25% for the challenge.

A group of 20 guinea pigs received topical doses of 1% P4150 under occlusive wrapping for 6 hours on days 1, 7 and 14. Irritation was assessed 24 hours after application. A control group of 20 guinea pigs received applications of distilled water. On day 28, a topical dose of 0.25% P4150 in distilled water was applied to a site on the flank of the animal opposite to that used for induction and an occlusive dressing applied for 24 hours.

The site was examined 24 and 48 hours after removal of the dressing. No redness or swelling occurred at the challenge site in any animals in either the test or the control group.

The notified chemical was found not to be a skin sensitiser in guinea pigs.

9.2 90-Day Repeated Dose Oral Toxicity Study

This test was carried out according to OECD Guidelines for Testing of Chemicals No: 408

P4150, corresponding to 30% active material, in purified water was administered by gavage once daily to groups of Wistar albino rats (10/sex) at dose levels of 5 (group 1), 10 (group 2), 30 (group 3) or 90 (group 4) mg/kg over 13 weeks. The control group received only purified water. Half of the animals in the control group and high dose groups after 13 weeks of treatment were subject to a four-week recovery period.

During the treatment phase of the study sanguineous salivation, increased activity and defensive movements were observed for a short time after each daily administration in group 4 animals while only salivation was observed in group 3 animals.

Two males and three females from the high dose group were accidentally killed between 7 to 12 weeks of the study.

Food consumption decreased in group 4 males and females, which persisted in the male group throughout the recovery period.

Dose related statistically significant reductions in body weight gains were observed in groups 3 and 4 males and females.

Clinical chemistry investigation revealed a significant dose-related increase of serum Aspartate-transferase values in males and females of group 3 and 4 and extremely high serum aminotransferase values in two males and three females in group 4. Only serum Aspartate-transferase values persisted throughout the recovery period.

Histopathological observations revealed irritant effects in the nasopharynx and stomach as well as local effects in the jejunum and mesenteric lymph nodes due to oral administration. No histopathological changes indicative of systemic toxicity were found.

At necropsy there was no significant organ weight changes attributable to treatment with the test material or significant treatment-related macroscopic changes observed in the study.

The study reveal at higher doses (30 and 90 mg/kg/day), a dose related increase in some liver enzymes, no treatment related effects at doses of 5 or 10 mg/kg/day.

9.2 Genotoxicity

9.2.1 *Salmonella typhimurium* Reverse Mutation Assay (12)

This test was carried out according to OECD Guidelines for Testing of Chemicals No: 471.

The mutagenicity of Lonzabac 12 (100% active material) was determined *in vitro in S.typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538. After a preliminary experiment to determine the bactericidal effects of the notified chemical, the following concentrations of Lonzabac 12 were chosen:

. with metabolic activation up to 150 ug/plate; and

. without metabolic activation up to 600 ug/plate.

Positive controls used were 2 nitrofluorene with TA98 and TA1535; sodium azide with TA100 and 1535; 9 aminoacridine with TA1537 without metabolic activation and 2 aminoanthracene with TA98, TA100 and TA1535 with metabolic activation.

Some toxic effects on bacterial growth were noted at high concentrations. No mutagenic effects were reported in any strain with or without metabolic activation. All positive controls were effective.

Lonzabac 12 was not found to be mutagenic toward *Salmonella. typhimurium*.

9.2.2. In Vitro Mammalian Cell Gene Mutation Test (13)

This test was carried out according to OECD Guidelines for Testing of Chemicals No: 476 (14).

The V79 cell line of the Chinese Hamster were used to determine the mutagenicity of Lonzabac 12 at the hypoxanthine-guanine-phosphoribosyl transferase (HPRT) locus. Cells were incubated for five hours with dilutions containing 5, 2.5, 1, 0.5, 0.1 and 0.5ug/ml of the 30% solution (Lonzabac 12.30) with and without S-9 metabolic activation.

At the end of the incubation period, the cells were transferred to fresh media for a three day period to allow expression of any induced mutation and a three day incubation in the selective agent (6-thioguanine) to determine mutant frequency. Negative controls use as expected were those cells exposed only to the incubation medium. Ethyl methane-sulfonate (EMS), without metabolic activation, and 7, 12 dimethyl-benzanthracene (DMBA), with metabolic activation, served as positive controls.

No increase in mutation frquency above background was observed at any dose.

It can be concluded that Lonzabac 12 is not mutageneic in this test.

9.2.3. In Vitro Mammalian cytogenetic test with Lonzabac 12.30 (15)

This test was carried out according to OECD Guidelines for Testing of Chemicals No: 476 (16).

This study was carried out in Chinese Hamster V79 cells. Concentrations of 0.1-10 ug/ml of the 30% active Lonzabac 12 were incubated for a five hour period, with and without metabolic activation. Cells were harvested after 17 and after 24 hours. Cyclophosphamide and methyl methanesulfonate (MMS) served as positive controls. Colcemid (10 ug/ml) was added two hours before the cells were harvested.

Examination of the cells showed that Lonzabac 12 did not cause any increase in chromosomal aberrations at any concentration, with or without metabolic activation. Cytotoxicity was seen at high concentrations. Cyclophosphamide produced the expected increase in the presence of metabolic activation and MMS without metabolic activation.

Lonzabac 12 was found not to induce chromosomal aberrations in Chinese Hamster V9 cells.

9.4 Overall Assessment of Toxicological Data

The acute oral LD_{50} in the rat was estimated to be ~ 260 mg/kg pure substance. Dermal LD_{50} was determined to be greater than 600 mg/kg pure substance. The notified chemical (in 30% concentration) is severely irritating/ corrosive to the skin but was not a sensitiser when tested in low concentrations.

A 90-day oral toxiicity study showed at higher doses (30 and 90 mg/kg/day), a dose related increase in some liver enzymes but, no treatment related effects at doses of 5 or 10 mg/kg/day.

It was not found to produce mutations in *S. typhimurium*, or the Chinese hamster V-79 cell line and there were no clastogenic effects in the Chinese hamster V-79 cell line.

On the basis of submitted data, the notified chemical would be classified as hazardous in accordance with Approved Criteria for Classifying Hazardous Substances in relation to Acute lethal effects (oral, dermal) and Irritant effects (skin).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following test results, using Lonzabac 12.30, were provided for aquatic species.

TEST	GUIDLINE	SPECIES	RESULT
Acute toxicity*	OECD No. 203 EEC 84/449	Rainbow trout *Salmo gairdneri*	96 h EC_{50}=2.3 ppm NOEC=0.76 ppm LOEC=1.4 ppm
Acute immobilisation#	OECD No. 202 EEC 84/449 C.2.	*Daphnia magna*	24 h EC_{50}=2.2 ppm EC0/NOEC=0.3 ppm EC 100=14.2 ppm

**Nominal concentrations made from a stock solution (of 400 mg.L^{-1}) were used. Test concentration in tanks varied from 113.9%-127.6% at the start of the trial to 67.2%-94.6% at completion (ie. 96 hours). The EC_{50} value was calculated using a logit model graph.*

 # Concentrations were determined to range between 176% to 91.3% of nominal from the beginning to the end of the test. The EC_{50} value was calculated using a logit model graph.

These results indicate that Lonzabac 12.30 is moderately toxic to the aquatic species examined.

The following test results, using Lonzabac 12.100, were provided for aquatic species.

TEST*	GUIDELINES	SPECIES	RESULT
96 hr Acute Static Toxicity**	OECD, ISBN, 92-84-12367-9 TSCA Title 40 of Fed. Reg, Part 797, Sect, 1400	Temperate Rainbow Trout, Oncorhynchus mykiss	96 hr LC_{50}=0.75 ppm NOEC=0.58 ppm
96 hr Acte Toxicity + 10 mg Humic Acid.L^{-1}***	TSCA Title 40 of Fed. Reg, Part 797, Sect. 1400	Temperate Rainbow Trout, Oncorhynchus mykiss	96 hr LC_{50}=3.0 ppm NOEC=1.4 ppm
96 hr Acte Toxicity + 20 mg Humic Acid.L^{-1}****	TSCA Title 40 of Fed. Reg, Part 797, Sect. 1400	Temperate Rainbow Trout, Oncorhynchus mykiss	96 hr LC_{50}=4.0 ppm NOEC=3.1 ppm
Growth Inhibition	Based on Title 40 Fed. Reg. Part 797, Section 1075 and ASTM Stand. Guide E 1218-90- Wildlife International Protocol No. 289/040692 SEL-96H_1/CHP39	Selenastrum capricornutum	96 hr EC_{50}=54 ppb NOEC=12 ppb

** All tests were conducted at nominal concentrations.*

*** 96% of fish exposed to 0.96 ppm Lonzabac 12.100 were dead within 24 hours, with all dead by 48 hours. At 1.6 ppm Lonzabac 12.100, 100% mortality occurred within 24 hours of exposure.*

**** 5% of tested fish died when exposed to 2.4 ppm during the 96 hour exposure, with 100% mortality at 4.0 ppm within 24 hours of exposure.*

***** 90% of fish exposed to 5.1 ppm Lonzabac 12.100 were dead at the end of the 96 hour period. At 8.5 ppm Lonzabac 12.100 100% mortality occurred within 24 hours.*

The above results indicate that Lonzabac 12.100 is moderately toxic to aquatic fauna which appears consistent with other tertiary amines (17). The presence of organic carbon in water (in the form of humic acid) reduces the toxicity to fish somewhat, as expected.

No data were supplied for *Daphnia* reproduction tests using either the pure or diluted substance, but chronic effects would not be expected in view of the limited persistence of the chemical.

The toxicity of the pure form of the notified substance to sensitive algae species (18) was high.

Tests were also conducted to determine if the effect of the test substance on algae was reversible. Experimental results indicated that Lonzabac 12.30 is algistatic, rather than algicidal, as the cell densities and growth rates at the highest level treatments (50 and 100 ppb) after 9 days in recovery solutions were equivalent to those parameters in the negative controls.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Environmental Hazard

The main route of environmental exposure for the notified substance will occur when spent Lonzabac in food and beverage manufacturers effluent is released to sewage plants and ultimately to receiving waters.

Food and beverage manufacturers are expected to have on-site effluent treatment plants (1,2), although these are most likely to be either promary or secondary treatment plants, and not tertiary as initially indicated by the notifier. The extent of degradation is expected to depend on the type of on-site treatment used.

A predicted environmental concentration (based on information provided by the notifier) can be calculated as shown below.

FACTOR	ASSUMING NO BIODEGRADATION
Estimated Use per day	6.8 kg
Appro. discharge from plant to on-site treatment plant*	189250 L
Expected concentration in waste water released from treatment to sewage treatment	36 ppm
Following dilution in sewage treatment water**	13.6 ppb

** Supplied by the notifier - page 6 of submission.*

*** Based on major public sewage treatment works where stream volumes are in the order of 500 ML.day*

Assuming no biodegradation, predicted release concentrations are generally 1-2 orders of magnitude below the levels of concern for most aquatic organisms (fish and invertebrates). However, concentrations are of concern to algae, since they are in the same order of magnitude as acute toxic and NOEC algistatic levels.

If a conservative estimate of 90% primary biodegradation is assumed then the predicted release concentrations will fall to below algistatic levels (ie ~ 1.4 ppb). Dilution in receiving waters will further reduce concentrations.

If Lonzabac were to be used in country areas (for example, Wodonga) where sewage treatment stream volumes are in the order of only 5 ML per day and the dilution factor in receiving waters are lower than for coastal areas, the PEC would be 1.36 ppm following sewage treatment (assuming no biodegradation). This is above the level of concern for some of the species tested. Assuming 90% primary biodegradation and a dilution factor of 2 in sluggish inland waterways during drought, the PEC reduces to 68 ppb, a level still toxic to algae.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

There is no information on the effects of Lonzabac 12.100 on human health. It has been shown in animal studies Lonzabac 12.100 and formulations containing it to have corrosive properties and posess the potential for severe skin, eye and respiratory damage if contact occurs. Skin irritation studies in rabbits showed that removal of the material containing the notified chemical from the skin was palliative. A 90 day oral toxicity study showed a treatment related effect at doses >30 mg/kg/day.

The transfer of formulated product from the blending tank to the vessel for application should be by mechanical pumping.

Considering the hazardous nature of the notified chemical all applications resulting in mist and spray should be carried out under local exhaust ventilation.

The public is unlikely to be exposed to the chemical, which will be imported and used as a corrosion inhibitor only in commercial processing equipment, with negligible waste discharge.

To confirm the above hazard assessment, the company should provide to the EPA yearly sales figures of Lonzabac 12.100/12.30, as well as more accurate discharge rates, and any further algal or Daphnia reproduction test data, as they become available.

13. RECOMMENDATIONS

The following guidelines and precautions should be observed when using Lonzabac 12:

. Local exhaust ventilation should be used in areas where mists or sprays of Lonzabac 12 may be generated.

. Personal protective equipment must be worn by all workers exposed to 100% active substance during shipping storage and transfer.

. If engineering controls and work practices are insufficient to reduce exposure to a safe level, the following personal protective equipment which complies with Australian Standards should be worn such as respiratory protection devices (AS 1715-1991 (19), AS 1716-1992 (20)), chemical splash goggles (AS 1336-1982 (21), AS 1337-1982 (22)) rubber or neoprene gloves (AS 2161-1978 (23) and overalls (AS 3765.1-1990 (24), AS 3765.2-1990 (25)).

. If skin contact occurs the material should be immediately removed with water.

. If eye contact occurs the eye should be held open and flushed with water for 15 minutes.

. Good housekeeping should be observed to minimise splashes and spills.

. Workers handling Lonzabac 12.100 or products containing it should have access to material safety data sheets (MSDS)

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for Lonzabac 12.100 (Attachment 1) was provided in Worksafe Australia format (26). This MSDS was provided by International Chemicals Pty Ltd, as part of their notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of International Chemicals Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of Lonzabac 12.100 shall be required under Section 64 (2) of the Act arises. Should Lonzabac 12.30 be proposed to be used in smaller provincial locations, secondary notification should occur, which should include data regarding accurate discharge rates, algal toxicity and *Daphnia* reproduction testing.

16. References

(1) Personal communication with Sydney Water Board.

(2) Personal communication with Melbourne Municipal Water Board.

(3) Organisation for Economic Co-operation and Development (1993). Structure-Activity Relationships for biodegradation. Draft. Environment Monograph No. 68. Paris.

(4) P4150: Acute Oral Toxicity Test in the Rat: Project No. 102/17. Data on File, Lonza Ltd. Munchensteinerstrasse 38, CH-4002, Basel, Switzerland.

(5) OECD Guidelines for testing of chemicals #401Acute oral toxicity.

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