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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

LONZABAC 12.100

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Director

Chemicals Notification and Assessment

FULL PUBLIC REPORT**LONZABAC 12.100****1. APPLICANT**

Chemical and Petroleum Industries Pty Ltd, 20 Ponting Street,
Williamstown, Victoria, 3016.

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; P4150

Trade names: Lonzabac 12.100 (100% actives)
Lonzabac 12.30 (30% actives)
Throughout this report "Lonzabac 12
" is used to refer to the active
component without implying
concentration.

Molecular formula: C₁₈H₄₁N₃

Structural formula:

Molecular weight: 299

Methods of detection and determination:

NMR, Infrared Spectroscopy, colourimetric analytical procedure;
Thin Layer Chromatography and Gas Chromatography.

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

Appearance at 20°C and 101.3 kPa:	Colourless to slightly yellow clear liquid.
Odour:	amine-like
Boiling Point:	275°C at 6 mm Hg (estimated)
Density:	870 kg/m^3
Vapour Pressure (predicted):	1.33×10^{-4} kPa at 25°C from homologue data
Water Solubility:	Soluble > 300 g/l
pH:	11.2 at 20°C (1% solution)
Partition Co-efficient (n-octanol/water) $\log P_{\text{OW}}$:	not measurable as the substance is a surfactant and would interfere with the determination by emulsifying the two phases
Hydrolysis as a function of pH:	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.

Adsorption/Desorption:

although no data have been provided, the substance's water miscibility suggests adsorption would be low. Biodegradation studies found low adsorption of Lonzabac to activated sludge.

Dissociation Constant:

No data have been provided. The substance, containing one tertiary and two secondary amine groups, will have basicity typical of these functionalities.

Flash Point:

estimated to be >110°C

Reactivity/Stability:

no isotherm was recorded when The dye was heated to 150°. Incompatible with aldehydes, nitrosating agents, concentrated strong acids and hypochlorite. Conditions that might contribute to physical instability and poor performance of the nominated substance under 'in use' conditions could include:

mixture with acids of any kind which would form salts with less efficient surfactant/lubricant properties

mixture with bacterial contamination which would lead to biodegradation and loss of foaming/surfactant properties

Surface tension: 30.5 mN/m for a 1% solution
(water =71 mN/m)

4. PURITY OF THE CHEMICAL

Degree of purity: 100% (distilled)

Toxic or hazardous impurities: It was stated that acrylonitrile, one of the starting materials was not detected (detection limit 5 ppm).

Non-hazardous impurities:
(> 1% by weight): None, n-propylamine is detected by GC-MS at <0.1%.

Additive/Adjuvant: None. Lonzabac 12.30 contains 70% water.

5. INDUSTRIAL USE

Lonzabac will be imported into Australia as either the pure distilled substance Lonzabac 12.100 or as Lonzabac 12.30 containing 30% of the pure substance. Quantities are expected to be less than 1 tonne/year for the first 5 years. The substance is listed in the Inventory of the European Community (EINECS) and has been used in the EEC for approximately 7 years. Anecdotal evidence shows no reports of related injury or disease.

The notified chemical will be used as a metal lubricant/corrosion inhibitor in gear chain applications in the food and beverage industry. The imported chemical will be sold by the notifier and reformulated with soaps and surfactants into a product containing 0.1 to 10 % concentrated Lonzabac 12.

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 chemical as a lubricant/corrosion inhibitor. The

substance used for formulation may be the 100% pure chemical. 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. Mechanical means are recommended for the transfer of Lonzabac 12.100 from one vessel or drum to another.

Protective equipment will be recommended when exposure to the pure substance occurs. Formulation may involve the exposure of 2-3 workers/site during transfer and cleaning of equipment.

Lonzabac 12 is present in the formulated product in concentrations of 0.1-10%. Again, transfer of the formulation from the blending tank to the vessel for application is recommended to take place by pumping.

Application 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

The substance is a specialty metal lubricant/corrosion inhibitor in gear chain lubricant formulations used in niche markets, such as in beverage bottling and packaging facilities. The compound will be imported.

The substance is transported in 55 gallon (250 L) steel drums with liner, the quantities transported varying from 1 to 20 drums, each drum containing 200 kg of the substance. The drums will be labelled to indicate the presence of a corrosive liquid but they will not require special storage conditions. In case of an accident during transportation and distribution or drum puncture during loading and unloading, it is claimed that the high biodegradability, 96% biodegraded within 12 days, ensures quick removal from the environment. Spills should be absorbed on appropriate solids and transferred to drums for disposal as accidental release into public water may result in toxicity to marine life. Incineration is the only recommended method of disposal. No release to sewers or open bodies of water is acceptable.

8. ENVIRONMENTAL EXPOSURE

. **Release**

Lonzabac 12 will be imported in 250 L lined steel containers and transported from point of entry, without repackaging or reformulation, to customers.

Barring the unlikely event of a major road or sea transport accident, spillages during product distribution are not expected. Disposal of unstated but probably low quantities of unused Lonzabac (container residues and spillages) is expected to be by incineration or secure landfill. It is emphasised by the company that no direct release of Lonzabac to sewers or watercourses should be allowed.

. **Fate**

Lonzabac 12 will be formulated at 0.1 to 10% in a facility blending tank and pumped to either a sprayer or a dip tank near a processing/assembly line. Based on information provided, each food and beverage manufacturing plant would be expected to consume 2.5 tonnes of the substance per annum.

Depending on the assembly-line configuration the gearing lubricant is recycled:

by gravity feed with application from a dip tank at the low end of the chain to allow drainage back to the tank; or

by spraying to inaccessible areas with drainage back to spray pump for respraying.

The testing for "spent" material involves a colorimetric determination using methylene blue. However, the decrease in lubricant foam height in the dip tank also provides a warning of mechanical degradation of Lonzabac before gearing noise begins. The product consumers will choose either test to monitor Lonzabac 12 degradation.

The spent aqueous gear chain formulation is discharged to on-site waste water processing where the notifier expects Lonzabac 12 to be significantly biodegraded.

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 biological oxygen demand/COD characterisation. This treatment process would be expected to assist in the biodegradation of remaining Lonzabac before discharge to the sewerage system. 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 and 2). However, on-site plants vary from primary, which use filtration and flotation to remove suspended material and solids, to tertiary water polishing ponds.

- **Bioaccumulation**

The notifier considers bioaccumulation testing unnecessary given the high biodegradation potential. This is acceptable as the notified substance's surface active properties would preclude testing under OECD 107 test guidelines.

- **Biodegradation**

The biodegradation of Lonzabac 12 was determined according to OECD Confirmatory Test Method Guideline 303A. This test determines the ultimate biodegradability of the test material under conditions which simulate treatment in an activated sludge plant. 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 12.

The biological ultimate degradability from the 12th day of the test reached an average of 96%.

9. EVALUATION OF TOXICOLOGICAL DATA

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, there is no requirement for toxicology testing on chemicals which are to be imported in quantities < 1 tonne/year. However the following tests were carried out and submitted as part of the notification statement.

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Lonzabac 12

Test	Species	Outcome	Ref
oral toxicity	rat	LD ₅₀ 280mg/kg (males) LD ₅₀ 245mg/kg (females)	(3)
dermal toxicity	rat	LD ₅₀ > 600mg/kg	(5)
skin irritation	rabbit	severely irritant/ corrosive	(7)
skin sensitisation	guinea pig	non-sensitising	(9)

9.1.1 Oral Toxicity (3)

This study was performed according to OECD Guidelines for Testing of Chemicals, Guideline 401 (4) using P4150 corresponding to Lonzabac 12.30.

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 1 male and 1 female rat. 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 male and 5 female). The animals were observed 1 and 4 hours post administration and daily thereafter for 14 days. Individual bodyweights were recorded on the day of treatment, days 7 and 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, all within 24 hours after dosing. Clinical signs and symptoms were hunched posture, piloerection, lethargy, slowed respiration and ptosis shortly after administration. Animals receiving 1000 or 2000 mg/kg also had increased salivation one hour after dosing. Weight gain in survivors was 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 animals dying during the study were abnormally red lungs, dark livers and kidneys, haemorrhage of the gastric mucosa and congestion of the small and large intestine.

The oral LD₅₀ of P4150 (Lonzac 12.30) was 933 mg/kg in males and 812 mg/kg in females. This corresponds to an LD₅₀ for the pure chemical of 280 mg/kg in males and 245 mg/kg in females.

9.1.2 Dermal Toxicity (5)

This test was carried out according to OECD Guideline #402 (6) using P4150, (corresponding to 30% active material). Five male and five female Sprague Dawley rats received doses of ~ 2 ml/kg, corresponding to 2000 mg/kg P4150, applied to an area of clipped skin corresponding to approximately 10% of the body surface area. The material was covered with a semi-occlusive dressing for 24 hours. Animals were observed for 14 days.

No deaths occurred during the study. Signs and symptoms were 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. No other abnormalities were reported at necropsy. Body weight gains were decreased during week 1 and one animal lost weight. All animals gained weight normally in week 2.

LD₅₀ was found to be > 2000 mg/kg P4150, corresponding to > 600 mg/kg of the pure notified chemical.

9.1.4 Skin Irritation (7)

This test was carried out according to OECD Guideline #404 (8). A quantity of 0.5 ml of P4150 containing 30% active material was applied to the clipped back of each of six New Zealand White rabbits and secured under a semi-occlusive dressing for four hours. Sites were examined 1, 24, 28 and 72 hours and 7 days following removal of the patches.

Observation 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.

Because the skin reaction was so severe after a 4 hour application, and to comply with overseas regulatory requirements to assign a risk phrase, the study was repeated with three minutes skin contact. Minimal irritation was noted.

The notified chemical was considered to be severely irritant/corrosive to the skin.

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 (9)

P4150, corresponding to 30% active material, was tested in albino Dunkin Hartley guinea pigs according to the Buehler method as described in OECD Guideline No. 406 (10).

After a preliminary experiment, which determined P4150 1.6% in distilled water to be the highest tested non-irritant concentration, the following concentrations were chosen:

induction	1% P4150 in distilled water
challenge	0.25% P4150 in distilled water

A group of 20 animals 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

animals 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 opposite flank of the animal and an occlusive dressing applied for 24 hours.

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

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

9.2 Genotoxicity

9.2.1 *Salmonella typhimurium* Reverse Mutation Assay (11)

The mutagenicity of Lonzabac 12 was determined in vitro against *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 (corresponding to 100% active material) were chosen:

with S-9 mix up to 150 ug/plate

without S-9 mix up to 600 ug/plate

Positive controls were:

- 2 nitrofluorene (2NF);
- sodium azide (NaN₃);
- 9 aminoacridine (AAC);
- 2 aminoanthracene (AAN);

Some toxic effects on bacterial growth were noted at high concentrations. No mutagenic effects were reported in any strain with or without the S-9 mix. All positive controls were effective.

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

9.2.2. In Vitro Mammalian Cell Gene Mutation Test (12)

The V79 cell line of the Chinese Hamster served as the cell line to determine the mutagenic effect of Lonzabac 12 on the hypoxanthine-guanine-phosphoribosyl transferase (HPRT) locus according to OECD Guideline #476 (13). 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 other 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, (if any). Negative controls were those cells exposed only to the incubation medium. Ethyl-methane-sulfonate (EMS), without S-9, and 7, 12 dimethyl-benzanthracene (DMBA), with S-9, served as positive controls.

No effect was observed at any concentration of the test substance indicating that the notified chemical has no effect on the HPRT locus and was not found to be mutagenic in this test.

9.2.3. In Vitro Mammalian cytogenetic test with Lonzabac 12.30 (14)

This study was carried out, in duplicate, in Chinese Hamster V79 cells according to OECD Guideline #476 (15). Concentrations of 0.1-10 ug/ml of the 30% active Lonzabac 12 were incubated for a five hour period, with and without S-9 metabolic activation. In the repeat experiment concentrations of up to 2.5 ug/ml were studied without S-9 and up to 10 ug/ml with S-9. Cells were harvested after 17 and after 24 hours. Cyclophosphamide and methyl-methane-sulfonate (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 in any concentration, with or without S-9 mix. Cytotoxicity was seen at high concentrations. Cyclophosphamide produced an increase in the presence of S-9 mix and MMS without S-9 mix. Lonzabac 12 was

found not to produce an increase in chromosomal aberrations in Chinese Hamster V9 cells.

9.4 Overall Assessment of Toxicological Data

The acute oral LD₅₀ in the rat was estimated to be ~ 260 mg/kg pure substance. Dermal LD₅₀ was determined to be greater than 600 mg/kg pure substance. Although rats in the dermal toxicity study exhibited systemic symptoms they were nonspecific and may not indicate absorption through the skin since severe skin irritation occurred during this study and the symptoms are consistent with pain caused by a severe irritant remaining in contact with 10% of skin area.

The notified chemical (in 30% concentration) is severely irritating/ corrosive to the skin but was not a sensitiser when tested in low concentrations. It must be assumed to have severe eye and respiratory irritant properties. 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.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following test results, obtained according to OECD Guidelines 203 and 202, were provided for aquatic species.

Test	Species	Result
Acute toxicity	Zebrafish	96h LC ₅₀ =2.26 mg.L ⁻¹
Acute Immobilisation	<i>Daphnia magna</i>	24h EC ₅₀ =2.21 mg.L ⁻¹

The above results indicate that Lonzabac 12 is moderately toxic to aquatic fauna which appears consistent with other tertiary amines eg N-dodecyl-di(aminoethyl)glycine and n-dodecylguanidineacetate (16).

No data were provided for algal growth inhibition or daphnia reproduction.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The main route of environmental exposure for the notified substance will occur when spent Lonzabac 12 in food and beverage manufacturers' effluent is released to sewage plants and ultimately to receiving waters. However, given the high potential for biodegradation, the substance is unlikely to persist in the environment.

These food and beverage manufacturers are expected to have on-site effluent treatment plants (1 and 2). This effluent would be expected to be biologically active, thus enhancing prospects for the substance's biodegradation prior to release to the environment and public sewer systems. However, the extent will depend on the type of on-site plant.

• Predicted environmental concentrations

A predicted environmental concentration can be calculated using the following assumptions :

- food and beverage manufacturers (the likely consumers) would be likely to use 2.5 tonnes of Lonzabac 12 per annum (8 kg per day);
- these manufacturers are expected to have on-site effluent plants for pretreatment (possibly including biodegradation) of food processing wastes ; and
- an effluent discharge of 200 kL.day⁻¹ is expected to contain 0.3 ppm Lonzabac 12.

It could be assumed that food and beverage manufacturers would be located near major urban areas or principal country regions (eg Albury-Wodonga) serviced by public sewage works where stream volumes are in the range 5 to 500 ML.day⁻¹ (17). Further dilution would be expected in a sewerage treatment plant to worst case concentrations of 120 ppb Lonzabac 12.

If 96% biodegradation of Lonzabac 12 occurs in the sewerage treatment plants, the likely substance concentration released to receiving waters will be 5 ppb.

. **Ecotoxicity hazard**

These concentrations are nearly 3 orders of magnitude less than the ecotoxicity results presented above and indicate Lonzabac 12 is unlikely to present either an acute or chronic hazard to aquatic invertebrates and freshwater fish at likely environmental levels. Although no algal toxicity results were provided for Lonzabac 12, the notified substance is also unlikely to present a hazard to algae.

If the notified substance does bind to sediment to some extent it is unlikely that significant toxic levels of the notified substance will occur due to its high water solubility and high biodegradation potential.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Lonzabac 12 and formulations containing it are corrosive chemicals and possess the potential for severe skin, eye and respiratory damage if contact occurs. Skin irritation studies in rabbits showed that removal of the material from the skin was palliative.

Workers at formulation plants and those involved in the storage and handling of the imported product will be exposed to the pure chemical or to 30% solutions.

The formulated chemical will be applied by dipping or by spraying. Although these workers will be exposed to a lower concentration (0.1-10%) the pH of a 1% solution (11.2) indicates that these solutions too will have strong irritant properties. Exposure by contact with mists and vapours when spraying or with the liquid should be avoided.

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 or products containing it are in use.

- . Formulators exposed to either the pure Lonzabac 12.100 or to Lonzabac 12.30 or products containing it should wear protective clothing conforming to AS 3765.1 (18) or 3765.2 (19), rubber or neoprene gloves which conform to AS 2161-1978 (20), chemical splash goggles conforming to AS 1337 - 1984 (21)
- . Workers who may be exposed to mists or sprays of Lonzabac 12.100 or products containing it should wear respiratory protection conforming to AS 1715-1991 (22)
- . 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 not provided in Worksafe Australia format (23). Before the chemical is introduced, specific respiratory protection should be recommended. This MSDS was provided by Chemical and Petroleum Industries 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 Chemical and Petroleum Industries Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of Lonzabac 12 shall be required under Section 64 (2) if the Australian market increases above 1 tonne import volume per annum.

The Director may require the provision of a full data set for environmental toxicology to include *Daphnia* reproduction and

algal growth inhibition studies, as set out in Part C of the Schedule in the Handbook for Notifiers.

16. **References**

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- (4) OECD Guidelines for testing of chemicals #401
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- (5) P4150: Acute Dermal Toxicity (Limited Test) in the
Rat. Project No. 102/48. Data on File, Lonza Ltd.
Muncheinsteinerstrasse 38, CH-4002, Basel, Switzerland.
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- (9) P4150 Buehler Contact Sensitisation Study in the Guinea
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- (12) In vitro mammalian cell gene mutation test with Lonzabac 12.30. Data on File, Lonza Ltd. Munchensteinerstrasse 38, CH-4002, Basel, Switzerland.
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- (17) DASET internal report (1988), "Australian Sewage Profile"
- (18) Australian Standard 3765.1-1990. Clothing for Protection against Hazardous Chemicals. Part 1: Protection against General or Specific Chemicals. Standards Association of Australia Pub. Sydney 1990.
- (19) Australian Standard 3765.2-1990. Clothing for Protection against Hazardous Chemicals. Part 2: Limited protection against specific chemicals. Standards Association of Australia Pub. Sydney 1990.
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- (21) Australian Standard 1337-1984. Eye Protectors for Industrial Applications. Standards Association of Australia Pub, Sydney 1984.

- (22) Australian Standard 1715-1991. Selection, Use and Maintenance of Respiratory Protective Devices. Standards Association of Australia Pub, Sydney 1991.
- (23) Guidance Note for Completion of a Material Safety Data Sheet. (NOHSC: 3001 (1991), 3rd Edition, October, 1991.