

## LOW REGULATORY CONCERN CHEMICALS (LRCC)

### Discussion Paper No. 2

#### **LOW RISK CRITERIA AND SCENARIOS FOR CONTROLLED USE PERMITS**

##### **1. PURPOSE**

The *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) was amended to provide a framework for the consideration of Low Regulatory Concern Chemicals (LRCC). Included in the amendments to the Act were special provisions for the introduction of new industrial chemicals that are considered a low risk under the Controlled Use Permit category and, secondly, broadening of the criteria for introduction of new chemicals under an Early Introduction Permit (EIP). This discussion paper seeks comment on:

- the proposed criteria to be used to classify chemicals as “low risk”;
- the proposal of the use of the criteria in the Controlled Use Permit system; and
- use of the criteria in the EIP system.

##### **2. BACKGROUND**

The LRCC Public Discussion Paper (May 2003) proposed that a new category and criteria for Controlled Use Permit be established. In the Explanatory Memorandum and the Regulatory Impact Statement for Proposed LRCC Amendments to the Act, it was proposed that the category be available to chemicals, which, either alone or in a mixture, or because of the way they are transported, handled, used and/or disposed, qualify as LRCC. The following parameters were proposed for assessing these chemicals and establishing that they present a low risk to human health and the environment due to limited potential exposure in Australia – one or more of the following may apply:

- Controlled transport and storage;
- Specialised uses;
- Low public, workplace and environmental exposure; and
- Containment in closed systems.

The implication for this permit notification category is that exposure is highly controlled, either through established good work practices, responsible disposal and compliance with all relevant chemicals regulations or through specific control measures designed to minimise exposure.

##### **2.1 Controlled Use Permit**

A key plank of the LRCC reform initiative was to provide incentives to industry to introduce new and safer technologies and chemicals. As part of this new assessment categories and controls were suggested specifically, Recommendation 6.1 of the LRCC Final Report called for:

*Examine the introduction of a controlled use/specified use assessment (permit/and or certificate) category based on the history of safe use, limited exposure and/or use in controlled environments.*

Under this category introducers of new industrial chemicals for use in a highly controlled manner may be granted a permit. Introduction must be of low risk to workers, the public and the environment. Safeguards have been incorporated into the permit system. Provision for the Controlled Use Permit system is in Division 1C of the Act, sections 22A to 22O.

Section 22A of the Act states that:

*The object of the controlled use permit system is (a) to provide an alternative to the assessment certificate system in respect of a new industrial chemical that is a low risk to occupational health and safety, public health, and the environment because of its use, handling and disposal are highly controlled, and (b) to ensure that this alternative is subject to adequate safeguards.*

### **3. PROPOSAL**

It is proposed to:

- include low risk (or exposure) criteria in the regulations;
- list acceptable low risk or exposure scenarios;
- introduce guidelines to enable use of the criteria for the introduction of highly controlled chemicals under the Controlled Use Permit;
- introduce guidelines to enable use of the criteria for the early introduction of highly controlled chemicals under the Early Introduction Permit; and
- develop safeguards to protect the health of the public, workers and the environment from the harmful effect of industrial chemicals.

Notifiers who can demonstrate that a chemical meets the low exposure criteria and/or the standard low exposure scenarios (for introduction, use, handling and disposal of the chemical) may apply for assessment of the chemical under the Controlled Use Permit system or early introduction under the EIP system.

#### **3.1 Low Risk Criteria**

Risk can be defined as the probability of an adverse effect in an organism, system, or (sub) population caused under specified circumstances by exposure to an agent (OECD, 2003). Fundamentally, when determining the risk posed by a chemical, two factors need to be considered; the severity of the hazard of the chemical and the level of exposure to the chemical.

It is proposed that the following criteria will be used to determine if a new industrial chemical poses a low risk for the purposes of the Controlled Use Permit and EIP:

##### **3.1.1 Hazard**

A number of limitations on hazard have been made for development of low risk criteria and scenarios; these apply to both low exposure criteria and specific low exposure scenarios.

Firstly, all the relevant hazards of the chemical must be known. Secondly, it is proposed that chemicals with similar properties to those prohibited or severely restricted under

Australia's international obligations would not be considered in this category as they are subject to bans or severe restrictions under different mechanisms. Further, new chemicals with persistent organic pollutant (POPS) characteristics, which include persistence and bioaccumulation, will not be considered a low risk for the purpose of the Controlled Use Permit category. In addition chemicals classified as carcinogenic, mutagenic, or reproductive toxicants (CMR chemicals) would not be considered a low risk for the purpose of the Controlled Use Permit category. This approach is consistent with that taken by other national regulatory schemes, e.g. in the EU and US.

Also, in general, it is proposed that a new chemical will not be introduced under this section if NICNAS determines that the chemical, any reasonably anticipated metabolites, environmental transformation products, or by-products of the chemicals, or any reasonably anticipated impurities in the chemical may cause, under anticipated conditions of manufacture, processing, distribution in commerce, use, or disposal of the new chemical:

- a. Serious acute (lethal or sublethal) effects;
- b. Serious chronic (including carcinogenic and teratogenic) effects; or
- c. Significant environmental effects.

Where:

*Serious acute effects* means:

human disease processes or other adverse effects that have short latency periods for development, result from short-term exposure, or are a combination of these factors and that are likely to result in death, severe or prolonged incapacitation, disfigurement, or severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities.

*Serious chronic effects* means:

human disease processes or other adverse effects that have long latency periods for development, result from long-term exposure, are long-term illnesses, or are a combination of these factors and that are likely to result in death, severe or prolonged incapacitation, disfigurement, or severe or prolonged loss of the ability to use a normal bodily or intellectual function with a consequent impairment of normal activities.

*Significant environmental effects* means:

- Any irreversible damage to biological, commercial, or agricultural resources of importance to society;
- Any reversible damage to biological, commercial, or agricultural resources of importance to society if the damage persists beyond a single generation of the damaged resource or beyond a single year; or
- Any known or reasonably anticipated loss of members of an endangered or threatened species.

### **3.1.2 Exposure**

It is proposed that all exposure scenarios for workers, the public and the environment are known and highly controlled for each known use.

i. Consumers and the general population

For exposure of consumers and the general population to the new chemical during all manufacturing, processing, distribution in commerce, use, and disposal of the chemical:

- a. No dermal exposure;
- b. No potential for oral exposure, i.e. from consumer products; and
- c. No inhalation exposure.

ii. Workers

For exposure of workers to the new chemical during all manufacturing, processing, distribution in commerce, use and disposal of the chemical:

- a. No dermal exposure (this criterion is met if adequate dermal exposure controls are used in accordance with applicable state and federal guidance); and
- b. No inhalation exposure (this criterion is considered to be met if adequate inhalation exposure controls are used in accordance with applicable state and federal guidance)

iii. Environment

Ambient surface water

For ambient surface water releases:

- a. No releases resulting in surface water concentrations above 1 part per billion

Atmosphere

For ambient air releases:

- b. No releases of the new chemical above 1 microgram per cubic metre maximum annual average concentration, calculated using the formula: (kg/day of release after treatment) x (number of release days per year) x (9.68 x 10<sup>-6</sup>) micrograms per cubic metre.

Land

For releases to land:

- c. No releases to land or to a landfill unless the introducer has demonstrated that the new chemical has negligible groundwater migration potential.

### 3.2 Factors to be considered in determining low risk scenarios:

A low risk scenario is one in which exposure is highly controlled at all stages (from cradle to grave) of the chemical's life cycle by:

- Appropriate packaging;
- Appropriate labelling and safety information;
- Appropriate handling procedures during processing;
- Appropriate treatment, handling, re-use, disposal of original packaging;
- Appropriate control of packaging waste;
- No release or appropriate control of production and cleaning waste;
- Control of occupational exposure during processing, packaging, cleaning/maintenance and use;

- Control of release of waste and residues to environment;
- Control of waste disposal and/or waste degradation processes; and
- Control of end-use of chemical to prevent public exposure.

Means of control for all uses of the chemical will need to be demonstrated by the notifier.

There is no upper limit on the introduction volume for Controlled Use Permit category. Control measures (as described) employed to restrict release and exposure must be demonstrated by the notifier. Additional data requirements will be required if more than 10 tonnes of the notified chemical is to be introduced.

The introduction volume and data requirements for an EIP are linked to the application for an assessment certificate in the relevant category.

### **3.3 Specific low exposure scenarios**

To assist in the application of the exposure component of the low risk criteria, two low exposure scenarios have been developed for inclusion in the guidance documents. The low exposure scenarios presented are familiar to NICNAS as a result of experience in assessing a number of new chemicals controlled in this manner. Notifiers may apply to introduce a new industrial chemical under the Controlled Use Permit if it can be demonstrated that the exposure is controlled at every stage of the chemical's lifecycle in accordance with the low exposure elements given in the low exposure scenarios. As low risk criteria contain both exposure and hazard elements, the hazard requirements stated above for the low risk criteria (section 3.1.1) will also need to be met. The low exposure scenarios are given in Appendix 1.

It is anticipated that further low risk scenarios will be determined by NICNAS on a case by case basis pending applications. Such precedent setting decision will be gazetted and added to guidance documents.

## **4. SAFEGUARDS**

Under Section 22A of the Act, a Controlled Use Permit is available for new industrial chemicals that are low risk to occupational health and safety, public health and environment because their use, handling and disposal are highly controlled. The applicants will need to demonstrate that the use, handling and disposal of the new chemical is highly controlled.

Under section 22F of the Act, the Director may reject an application for a Controlled Use Permit if not satisfied that (a) sufficient data have been provided for assessment and (b) use of the chemical satisfies the criterion of 'no unreasonable risk to occupational health and safety, public health and the environment'. Guidance for 'no unreasonable risk' has already been developed by NICNAS and is used to determine if introducers of new chemical need to apply assessment permit or certificate.

Under the permit system in NICNAS, conditions may be applied to the permit to ensure that use of the chemical will not result in any unreasonable risk to workers, the public, or the environment. The conditions may refer to any aspect of the chemical's manufacture, handling, storage, use, or disposal. The conditions may also specify special packaging

and labelling requirements and procedures relating to potential release of the chemical or its waste products into the environment. Standard conditions currently applied to permits acknowledge the role of States and Territory legislation in enforcing workplace and environmental controls.

Under the permit system, the conditions on the permit are binding, not only on the applicant, but any user of the chemical. The conditions on the permit can also be varied by the Director at any time. If any condition on a permit is breached, the permit may be withdrawn by the Director and/or a penalty imposed.

As with other permits issued by NICNAS, Controlled Use Permits will be subject to audit by the NICNAS compliance team. Penalties apply for failure to meet conditions on the permit, for example, exceeding the maximum volume of introduction specified on the permit.

Under the new annual reporting requirements in the Act (Division 3B), holders of Controlled Use Permits will be required to keep records of any application for 5 years after issue of the permit. Holders of the permit must also submit an annual report to NICNAS including details of the chemical's name and volume and any information about adverse effects of the chemical on occupational health and safety, public health and the environment.

Similar safeguards apply for EIP applications.

## **6. PROPOSED GUIDELINES FOR USE OF LOW RISK CRITERIA IN CONTROLLED USE PERMIT APPLICATIONS**

### **6.1 Information Required in Application**

The information required by NICNAS with an application for a Controlled Use Permit is listed in subsection 22C(2) of the Act, namely:

- all proposed uses of the chemical;
- a summary of the chemical's effects on occupational health and safety, public health and the environment;
- the volume to be introduced over a 3-year period.

The summary of health and environmental effects requires consideration of the chemical's health and environmental hazards and an estimate of the impact of the chemical on workers, the public and the environment. A legislative condition of the permit is that there be low risk to occupational health and safety, public health and the environment.

Paragraph 22C(2)(e) allows for further data requirements in the regulations and, for an application for the Controlled Use Permit, the following items are proposed:

- information on chemical identity, as in Part B.1 of the Schedule to the Act (for polymers, typical molecular weight data would be required);

- summary of how the chemical meets the definition of hazardous chemical in the Act;
- details of any notification of the chemical in another country;
- concentration of the chemical in products;
- exposure of workers, public and to the environment as in Part B (items 6, 7, 8) of the Schedule;
- detailed information on how the chemical is controlled, e.g. methods of control to prevent release into the workplace, community and the environment (the Controlled Use Permit is only for chemicals which are ‘highly controlled’, so this must be demonstrated by the applicant);
- precautions taken for safe storage and transport;
- information on emergency procedures, as in Part B.13 of the Schedule;
- label and MSDS for the chemical and products containing the chemical.
- For volumes exceeding 10 tonnes per year, it is proposed that all available toxicological and ecotoxicological data be provided with notification.

Under section 22D of the Act, the Director may request further information about the application.

The required data may be measured data, analogue data, accepted predictive models, and QSAR. Chemicals that are close analogues of previously assessed chemicals and to be used in the same way could be eligible if the read across assessment indicate that the new chemical is a low risk.

Chemicals for which overseas assessments are available from recognised overseas regulatory agencies may be considered for a Controlled Use Permit if the international assessment indicates that the new chemical is a low risk. The assessed use of the chemical must be same as the proposed Australian use.

In summary, the information requirements are similar to those required for other types of permit applications.

Guidance will be provided in the NICNAS Handbook for Notifiers to assist applicants in submitting their application.

## **6. GUIDELINES FOR USE OF LOW RISK CRITERIA IN EIP APPLICATIONS**

The information required for use of the EIP system will be in accordance with that required for the relevant assessment certificate category. Detailed information on how the chemical is controlled will be required in the notification statement.

## **7. FURTHER INFORMATION**

For information regarding the notice or matters regarding chemicals for Controlled Use Permit, please contact Bob Graf on 02 8577 8850 (e-mail [bob.graf@nicnas.gov.au](mailto:bob.graf@nicnas.gov.au)).

### **References**

OECD 2003 OECD Environment, Health and Safety Publications Series on Testing and Assessment No.44 Descriptions of Selected Key Generic Terms Used in Chemical Hazard/Risk Assessment Joint Project with IPCS on the Harmonisation of Hazard/Risk Assessment Terminology October 2003.

## APPENDIX 1

### NICNAS Low Exposure Scenario 1 – Containment and Controlled Reformulation

- Use

Chemical additive or polymer chemical imported for incorporation into masterbatch or polymer concentrates for the plastics industry.

- Exposure Scenario

- Main route of workplace exposure

Potential skin contact or inhalation exposure when packaged substances are opened and measured/ weighed by members of the workforce for addition of the new chemical to mixing vessels or loss in weight feeders for introduction to masterbatch extruders.

Subsequent exposure eliminated due to extrusion taking place in closed system and incorporation of new chemical in a bound, non-bioavailable state in a polymer matrix.

Transport and warehouse workers only exposed in the event of accidental breach of packaging.

- Main route of public exposure

The new chemical will not be available in technical state for use by the public. Potential skin contact when finished moulded articles containing the bound, non-bioavailable chemical are handled by members of the public.

Public exposure only possible in the event of release of the chemical after a transport incident.

- Main route of environmental exposure

No intentional release of the new chemical to the aquatic, air or terrestrial environmental compartments. Waste chemical can be generated from residues in packaging and when bound and not bioavailable in non-recyclable polymer matrix and when captured in dust/ vapour extraction filters. All residues disposed of by licensed waste disposal companies to approved hazardous waste landfill.

Environmental exposure only possible in the event of release of the chemical after a transport incident.

- Risk Management Measures

Demonstration of controlled exposure at all stages of chemical life cycle.

- Controlled transport and storage

New chemical to be packaged in dangerous goods-approved packaging or in robust packaging suitable for protection and retention of the contents.

Packaging to be transported by road or rail as dangerous goods according to the Australian Code for Transport of Dangerous Goods by Road and Rail, if appropriate, or transported by recognised industrial chemicals transport operators.

Packaging to be stored in dangerous goods stores that are approved under States and Territories legislation, or stored in general industrial chemicals stores controlled by experienced stores operators and in a location to prevent damage to packaging and release to drains, sewer or to the soil.

- Appropriate packaging

New chemical to be packaged in dangerous goods-approved packaging or in robust packaging suitable for protection and retention of the contents.

- Appropriate labelling and safety information

Packaging to be labelled according to the NOHSC National Code of Practice for the Labelling of Workplace Hazardous Substances.

- Appropriate handling procedures during processing or specialised uses

Handling operations when packaging is opened for access to the new chemical must be carried out in designated areas by trained operators who have had specific training relating to the new chemical or to products containing the new substance. All operators to be trained in the appropriate operational procedures and precautions.

The designated handling areas must be serviced with general and local exhaust ventilation and operators must have appropriate personal protective equipment (clothing (impervious if necessary), impervious gloves, safety eyewear and breathing protection (dust mask, filter apparatus or air-supplied apparatus, as necessary)) available for use during handling operations.

Processing will involve supervision of automated closed or semi-closed systems. Intervention in operations may occur but appropriate ventilation and personal protection to be used.

- Appropriate treatment, handling, re-use, disposal of original packaging

Original packaging for the new chemical is expected to retain chemical

residues after emptying for use in production. Empty packaging and any residues to be disposed of to regulated landfill.

- Appropriate control of production cleaning waste

Quantities of the new chemical spilled or remaining from batch production will be collected and placed into sealable containers for reuse or for disposal.

The new chemical will be incorporated in polymer substrate during production. Waste generated during setting of initial extrusion specifications or from off-specification material and from cleaning/ purging at the end of production runs will be either collected for recycling or for disposal.

All production and cleaning waste collected for disposal will be sent to a regulated landfill.

- Control of occupational exposure during processing, packaging and cleaning/maintenance.
- Control of exposure in accordance with hierarchy of controls in federal and state/territory OHS legislation and Codes of Practice.

If required transport, warehouse and stores personnel will wear personal protective equipment appropriate to the tasks when receiving and handling consignments of the new chemical in closed packaging

The operations for measuring of batches of the new chemical and supervision of blending and extrusion will take place under local exhaust ventilation. Batch addition of the new chemical to extruder machines may take place automatically using a loss-in-weight feeder. Blending and extrusion will take place in automated semi-enclosed systems with the new chemical immobilised in solidified polymer prior to packaging. Production and quality control operators involved in handling of the new chemical and handling of extruded pellets that contain the chemical will wear personal protective equipment appropriate to the tasks.

Packaging of blended and extruded pellets that incorporate the new chemical will involve use of safety gloves if handling of pellets is necessary.

Cleaning/ Maintenance operations will be conducted after purging processes have been completed. Purge polymer may contain immobilised new chemical and will be handled using safety gloves after solidification of the polymer.

- Control of occupational exposure by education and training

Standard work practices are established for use of polymer additives by the end-user. These practices require a copy of the Material Safety Data Sheet to be available for all new materials.

Appropriate precautions and personal protective equipment are determined

from the MSDS.

Occupational exposure will be controlled to prevent occupational risks by use of appropriate engineering controls, personal protective equipment and workplace training.

- Control of release of waste, residues to environment

Release of the new chemical during manufacture of the chemical will not occur as the chemical will not be manufactured in Australia.

Release of the new chemical during shipping, transportation and storage will only occur due to accidental spillage or leakage from packaging. The packaging of the chemical is appropriate to ensure release is not likely.

Residual chemical retained in packaging will be disposed of with the empty packaging to regulated landfill.

Waste chemical generated during extrusion processes will be a minor proportion of the introduced substance. Quantities of waste chemical may arise from spillage prior to blending or from waste extruded preparations that are not able to be recycled. The waste will be collected and consigned to regulated landfill.

All of solid wastes generated that contain the new chemical will either be disposed of to landfill or recycled.

- Control of waste disposal and/or waste degradation processes

The use and disposal pattern for the new chemical is such that direct release to the aquatic, air and terrestrial environmental compartments is not expected.

The majority of the new chemical will be contained in a polymer matrix either as production waste or as moulded articles.

Disposal procedures should be in accordance with Government regulations. Waste from production and at the end of the life of moulded articles will either be recycled, released to regulated landfill sites or incinerated.

The chemical when incorporated in the inert polymer matrix and released to regulated landfill sites will not be directly released to the environment. The chemical held within the polymer substrate will not be readily mobile and will slowly undergo abiotic and biotic degradation after disposal to landfill.

The potential for exposure of the new chemical to the environment is highly controlled to ensure risk to the environment will be low.

- Control of end-use of new chemical to ensure low public exposure

The new chemical will only be used industrially and will not be available for

direct purchase or use by members of the public.

Polymer preparations containing the new chemical will be used to mould end-use articles that may be used or accessed by the public. The chemical will be bound in the polymer system after reformulation into pellets and after moulding of the end-use articles.

The potential for exposure of the general public to the new chemical during transportation, storage, handling and manufacture operations will be minimal. Only in extreme cases of inappropriate handling or accidents during transportation would there be any likelihood of the new chemical being released from the packaging and the public being exposed.

The general public will only be exposed to the new chemical when using or accessing moulded end-use articles that contain the substance. When incorporated in the end-use articles, the new chemical will not be biologically available and will be of low risk to the public.

The public risk from exposure to the new chemical through all stages of its life cycle is considered to be low.

## **NICNAS Low Exposure Scenario 2 – Site-Limited and Closed System**

- Use

Industrial chemical intermediate imported for use and total consumption at one site in chemical synthesis process.

- Exposure Scenario

- Main route of workplace exposure

Potential skin contact or inhalation exposure when packaged substances are opened for pumping/ weighing by members of the workforce for addition of the new chemical to enclosed reaction vessels.

Subsequent exposure eliminated due to chemical reaction taking place in closed reaction vessel. New chemical consumed in process and no residues remaining in final product or in vessel.

Transport and warehouse workers only exposed in the event of accidental breach of packaging.

- Main route of public exposure

The new chemical will not be available in technical state for use by the public. The chemical will not exist after end-use chemical reaction.

Public exposure only possible in the event of release of the chemical after a transport incident.

- Main route of environmental exposure

No intentional release of the new chemical to the aquatic, air or terrestrial environmental compartments.

Waste chemical can be generated from residues in packaging. All residues from packaging will be either incinerated as part of packaging recycling processes or disposed of by licensed waste disposal companies to approved hazardous waste landfill.

Environmental exposure only possible in the event of release of the chemical after a transport incident.

- Risk Management Measures

Demonstration of controlled exposure at all stages of chemical life cycle.

- Controlled transport and storage

New chemical to be packaged in dangerous goods-approved packaging or in

robust packaging suitable for protection and retention of the contents.

Packaging to be transported by road or rail as dangerous goods according to the Australian Code for Transport of Dangerous Goods by Road and Rail, if appropriate, or to be transported by recognised industrial chemicals transport operators.

Packaging to be stored in dangerous goods stores that are approved under States and Territories legislation, or to be stored in general industrial chemicals stores controlled by experienced stores operators and in a location to prevent damage to packaging and release to drains, sewer or to the soil.

- Appropriate packaging

New chemical to be packaged in dangerous goods-approved packaging or in robust packaging suitable for protection and retention of the contents.

- Appropriate labelling and safety information

Packaging to be labelled according to the NOHSC National Code of Practice for the Labelling of Workplace Hazardous Substances.

- Appropriate handling procedures during processing or specialised uses

Handling operations when packaging is opened for access to the new chemical must be carried out in designated areas by trained operators who have had specific training relating to the new chemical or to products containing the new substance. All operators to be trained in the appropriate operational procedures and precautions.

The designated handling areas must be serviced with general and local exhaust ventilation and operators must have appropriate personal protective equipment (clothing (impervious if necessary), impervious gloves, safety eyewear and breathing protection (dust mask, filter apparatus or air-supplied apparatus, as necessary)) available for use during handling operations.

Processing will involve operations to pump or weigh the new chemical for addition to automated closed reaction vessels. Intervention in the reaction process will not occur after charging of reaction vessels.

- Appropriate treatment, handling, re-use, disposal of original packaging

Original packaging for the new chemical is expected to retain chemical residues after emptying for use in production. Empty packaging and any residues to be incinerated during package recycling or to be disposed of to regulated landfill.

- Appropriate control of production cleaning waste

Quantities of the new chemical spilled or remaining from batch production

will be collected and placed into sealable containers for reuse or for disposal.

The new chemical will be totally consumed during production. No residues of the chemical will remain in reaction vessels or be present in the final product after completion of the reaction due to the other excess starting reactants.

All production and cleaning waste collected for disposal will be either incinerated or sent to a regulated landfill.

- Control of occupational exposure during processing, packaging and cleaning/maintenance
- Control of exposure in accordance with hierarchy of controls in federal and state/territory OHS legislation and Codes of Practice.

If required transport, warehouse and stores personnel will wear personal protective equipment appropriate to the tasks when receiving and handling consignments of the new chemical in closed packaging.

The operations for pumping and measuring of batches of the new chemical and supervision of charging of vessels will take place under local exhaust ventilation. Batch addition of the new chemical to vessels may take place automatically from feeder tanks or via remote control of pumping processes. Chemical reaction will take place in automated enclosed vessels under controlled reaction conditions. No exposure to the new chemical will be possible when the reaction vessel is charged. Production and quality control operators involved in handling of the new chemical and handling of finished products manufactured from the chemical will wear personal protective equipment appropriate to the tasks.

Packaging of the finished product based on the new chemical will be carried out automatically with sealing of packages or containers involving operator involvement.

Cleaning/ Maintenance operations for vessels will be conducted after automated wash/ rinse processes have been completed. Rinsate will not contain residues of the new substance. Appropriate personal protective equipment will be used during cleaning/ maintenance procedures.

- Control of occupational exposure by education and training

Standard work practices are established for reaction processes by the end-user. These practices involve procedures for reaction vessel processes and require a copy of the Material Safety Data Sheet to be available for all new materials.

Appropriate precautions and personal protective equipment for new substances are determined from the MSDS.

Occupational exposure will be controlled to prevent occupational risks by use of appropriate engineering controls, personal protective equipment and

workplace training.

- Control of release of waste, residues to environment

Release of the new chemical during manufacture of the chemical will not occur as the chemical will not be manufactured in Australia.

Release of the new chemical during shipping, transportation and storage will only occur due to accidental spillage or leakage from packaging. The packaging of the chemical is appropriate to ensure release is not likely.

Small amounts of residual chemical retained in packaging after rinsing will be disposed of either by incineration during recycling of packages or disposed of with the empty packaging to regulated landfill.

- Control of waste disposal and/or waste degradation processes

The use and disposal pattern for the new chemical is such that direct release to the aquatic, air and terrestrial environmental compartments is not expected.

During manufacture of the end-use product the new chemical will be consumed. Therefore, the only sites of release will be import container residues, atmospheric release from transfers and from mixing vessels and spills.

Container rinsate with residues of the chemical will be transferred to an onsite effluent treatment plant. Atmospheric release will be captured by the local and general exhaust system with contaminants removed by a scrubber system and scrubber water also removed to the effluent treatment plant. Spills will be collected in sealable containers and disposed of either to a regulated landfill site, by incineration or retained in an onsite effluent treatment plant.

The potential for exposure of the chemical to the environment is highly controlled to ensure low risk to the environment will occur.

- Control of end-use of chemical to ensure low public exposure

The new chemical will only be used industrially and will not be available for direct purchase or use by members of the public. The chemical will be used entirely in the manufacturing process as a reactant that will be totally consumed to produce the end-use product.

The potential for exposure of the general public to the new chemical during transportation, storage, handling and manufacture operations will be minimal. Transport and storage as general industrial chemicals will provide satisfactory protection from exposure to the general public. Only in extreme cases of inappropriate handling or accidents during transportation would there be any likelihood of the new chemical being released from the packaging and the public being exposed.

The new chemical will only be used industrially and will not be available for direct purchase or use by members of the public. The chemical will be used entirely in the manufacturing process as a reactant that will be totally consumed to produce the end-use product.

The public risk from exposure to the new chemical through all stages of its life cycle is considered to be low.