Environmental Protection Authority
Te Mana Rauhī Taiao

DECISION

5 November 2018

Summary

Substance	Dytek A amine
Application code	APP203352
Application type	To import or manufacture for release any hazardous substance under Section 28 of the Hazardous Substances and New Organisms Act 1996 (“the Act”)
Applicant	Chemiplas NZ Limited
Purpose of the application	To import for release Dytek A amine, a single chemical used in epoxy curing systems
Date application formally received	2 October 2018
Consideration date	2 November 2018 – 5 November 2018
Considered by	The General Manager[1] of the Hazardous Substances and New Organisms group of the Environmental Protection Authority (“the EPA”)
Decision	**Approved with controls**
Approval code	**HSR101315**
Hazard classifications	3.1D, 6.1D (oral, dermal, inhalation), 6.9B, 8.2A, 8.3A, 9.1D

[1] The General Manager of the HSNO group of the EPA has made the decision on this application under delegated authority in accordance with section 19 of the Act.

1. Substance

1.1. Dytek A amine is a single chemical, 1,5-pentadiamine, 2methyl-, intended to be used as a chemical intermediate in epoxy curing systems. It is intended to be imported and used by professional users.

2. Process and consultation

Application receipt

2.1. The application was formally received on 2 October 2018 under section 28 of the Act.

Information available for consideration

2.2. The information available for the consideration comprised:

- the application form
- the confidential appendices to the application
- the EPA staff advice memorandum.

2.3. There was sufficient information to assess the application.

Public notification

2.4. This application was not publicly notified under section 53(2) of the Act because it was unlikely that there would be significant public interest in the application.

Notification to government departments

2.5. In line with section 53(4) of the Act, as the application was not publicly notified under section 53(2) of the Act, government departments were equally not notified of the application for Dytek A amine.

Legislative criteria for the application

2.6. The application was considered under section 29 of the Act, taking into account other relevant sections of the Act, the Hazardous Substances Regulations, the EPA Notices, the HSW Act and HSW (HS) Regulations and the Hazardous Substances and New Organisms (Methodology) Order 1998.

3. Hazardous properties of Dytek A amine

3.1. The hazard classifications of Dytek A amine were determined based on the information provided by the applicant (including proven access to the ECHA REACH registration dossier of 1,5-pentadiamine, 2methyl-).

3.2. The classifications that have been applied to this substance are the same as those submitted by the applicant (Table 1).

Table 1: Hazard classifications of Dytek A amine

Hazard	Applicant classification	EPA classification
Flammable liquid	3.1D	3.1D
Acute toxicity (oral)	6.1D	6.1D
Acute toxicity (dermal)	6.1D	6.1D
Acute toxicity (inhalation)	6.1D	6.1D
Skin corrosivity	8.2A	8.2A
Eye corrosivity	8.3A	8.3A
Target organ or systemic toxicity (inhalation)	6.9B	6.9B
Aquatic ecotoxicity	9.1D	9.1D

4. Risk and benefit assessment

Risk assessment

4.1. The risk assessment has taken into account the hazardous properties of the substance, the considerations in Part 2 of the Act, the prescribed controls under the Act and the requirements under other relevant legislation such as the HSW Act, Land Transport Rule 45001, Civil Aviation Act 1990 and Maritime Transport Act 1994.

4.2. The human health and environmental risks have been assessed in accordance with Section 29(1) of the Act. This assessment takes into account the full life cycle of this substance, including import, transport, storage, use and disposal.

4.3. The EPA staff determined that there is a low potential for exposure to people and the environment during the use phase of Dytek A amine.

4.4. Dytek A amine is made of a single chemical, 1,5-pentadiamine, 2methyl-, which is listed in the New Zealand Inventory of Chemicals (NZIoC) and may be used as a component in a product covered by a group standard, but which is not approved for use as a chemical in its own right.

4.5. There are other single chemicals used in epoxy curing systems, already HSNO approved, such as diethylene triamine (HSR002966), that can be used in their own right. The classification of some of those single chemicals (including diethylene triamine) is higher than the classification of Dytek A amine. Accordingly, the risks to human health and the environment are not likely to be significantly higher from the use of Dytek A amine compared to other approved substances used in similar ways. Therefore, the assessment of risks to human health and the environment for Dytek A amine has been limited to a qualitative assessment.

4.6. The risk and benefit assessment:

- considered the risks posed by Dytek A amine

- determined whether the risks are outweighed by the benefits
- determined whether any variations, additions to or deletion of the prescribed controls are required to manage the risks of the substance.

Assessment of physical risks

4.7. Dytek A amine is classified as a flammable liquid and could cause damage in the instance of a spill or leak of the substance in presence of an ignition source. The magnitude of this effect would be **moderate**. The prescribed controls under HSW (HS) regulations and other relevant legislation specifically address risks associated with the flammability of this substance during storage, transport, use, disposal and in the event of an emergency. Therefore, the likelihood of an event of this nature occurring during the life cycle of this substance would be **highly improbable**. Accordingly, the level of residual risk from the physical hazards of Dytek A amine is **negligible**, provided that the prescribed controls are in place and complied with.

Assessment of risks to human health

4.8. Dytek A amine is intended to be supplied to the professional market. Users are expected to add the substance in epoxy curing systems. Since the use is restricted to the professional markets, operators handling Dytek A amine are expected to have access to the Safety Data Sheet (SDS) of the substance, to wear appropriate personal protective equipment (PPE) as per the prescribed requirements under Health and Safety at Work Regulation 13.8 and to be trained to handle chemicals.

4.9. Dytek A amine has a lower hazard classification than currently approved substances with a similar use pattern.

4.10. There are prescribed requirements under HSW to use PPE to minimise risks to the health and safety of workers, therefore the EPA advises that the person conducting business or undertaking (PCBU) recommends the use of full personal protective equipment (PPE) to meet their obligations under regulation 13.8 of the HSW (HS) Act. This information about personal protection must be included in the SDS in accordance with sections 7 and 8 of Schedule 1 of the SDS Notice 2017. With prescribed controls and requirements, the residual level of risk from acute toxicity has been assessed as being **negligible**.

Assessment of risks to the environment

4.11. Given the use pattern of Dytek A amine, it is **very unlikely** that aquatic organisms will be exposed to the substance. Dytek A amine is classified as slightly harmful to aquatic organisms and as such it is expected that exposure may result in **minimal** effect to organisms. The prescribed controls include requirements for labelling and use, therefore the residual risk from the aquatic ecotoxicity hazard is assessed as being **negligible**.

Assessment of risks to Māori and their relationship to the environment

4.12. The potential effect of Dytek A amine on the relationship of Māori to the environment has been assessed in accordance with sections 5(b), 6(d) and 8 of the Act. Under these sections all persons exercising functions, powers, and duties under the Act shall:

- recognise and provide for the maintenance and enhancement of people and communities to provide for their cultural well-being, and
- take into account the relationship of Māori and their culture and traditions with their ancestral lands, water, taonga and the principles of The Treaty of Waitangi (Te Tiriti o Waitangi).

4.13. Findings of the cultural risk assessment (CRA) for Dytek A amine in relation to the above HSNO provisions are summarised below.

Section 5(b) – Recognise and provide for cultural well-being

4.14. This application is not likely to put the cultural well-being of Māori at risk in terms of their cultural beliefs and environmental frameworks.

Section 6(d) – Take into account Māori relationship to the environment

4.15. The CRA for Dytek A amine considered potential risks and impacts on Māori interests including the relationship of Māori to the environment, culturally significant species and resources, and the tikanga (customary values and practices) associated with these taonga. The CRA has identified cultural concerns in relation to taha hauora (human health and well-being) and culturally significant species, in particular food species. However, potential risks around these issues can be managed, therefore the application is not inconsistent with Māori cultural beliefs and environmental frameworks.

Section 8 – Take into account Treaty of Waitangi principles

4.16. For the EPA, as a Crown agency, this includes the duty to actively protect Māori interests, and ensure that EPA decision making is informed by Māori perspectives. The CRA has assessed cultural risk and identified how Māori interests will be protected.

Assessment of risks to society, the community and the market economy

4.17. No risks to society, communities or the market economy from the approval of Dytek A amine have been identified.

New Zealand's international obligations

4.18. No international obligations that may be impacted by the approval of Dytek A amine have been identified.

The effects of the substance being unavailable

4.19. The likely effects of Dytek A amine being unavailable in accordance with section 29(1) of the Act have been considered. Should Dytek A amine not be available, it could lead to less consumer choice.

Assessment of benefits

4.20. The applicant considers that the approval of Dytek A amine will provide the following benefits:

- Dytek A amine will contribute to improving the intrinsic properties of epoxy protective coating/flooring compounds compared to other chemical intermediates already available on the market and used in similar ways.
- Dytek A amine has a more desirable hazard profile compared to other chemical intermediates already available on the market and used in similar ways.

4.21. Although the benefits identified above were not verified by the EPA, it is considered that the availability of Dytek A amine will provide beneficial economic effects for some businesses with the potential for flow-on effects to local communities and the New Zealand economy, including improved consumer choice and greater market competition.

5. Prescribed controls

5.1. The hazard classifications of Dytek A amine determine a set of prescribed controls, specified by the EPA Notices[2] under section 77 of the Act. There are also requirements in the HSW (HS) Regulations. Note: the HSW (HS) requirements are not set for the substance under this approval but apply in their own right.

5.2. The prescribed controls set the baseline for how the substance must be managed and include specifications on how the substance is to be packaged, labelled, stored, disposed, transported, handled and used. The prescribed controls also set information requirements (eg Safety Data Sheets), signage and emergency management. These controls form the basis of the controls specified in Appendix A.

5.3. Clause 17 of the Labelling Notice requires that certain toxic or corrosive components are identified on the product label. Schedule 1, section 3 of the SDS Notice requires certain toxic or corrosive components are identified on the Safety Data Sheet (SDS).

5.4. The name and concentration of the following components need to be specified on the label and SDS:

Table 2: List of components requiring identification

Label	SDS
1,5-pentadiamine, 2methyl- [6.1D (oral, dermal, inhalation), 6.1E, 6.9B, 8.2A, 8.3A]	1,5-pentadiamine, 2methyl- [6.1D (oral, dermal, inhalation), 6.1E, 6.9B, 8.2A, 8.3A, 9.1D]

[2] There may also be default controls in regulations made under the Act for certain hazardous substances such as fireworks.

Exposure limits

5.5. Under s77B of the Act, the EPA may set a Tolerable Exposure Limit (TEL) and/or an Environmental Exposure Limit (EEL) for a substance with toxic or ecotoxic properties.

- Regulation 13.17 of the HSW (HS) Regulations prohibits the use of a class 6 substance in excess of a TEL.
- Clause 49 of the Hazardous Property Controls Notice prohibits use of a class 9 substance in excess of an EEL.

5.6. No TEL for Dytek A amine is set as exposure to this substance is not likely to result in an appreciable toxic effect to people, provided controls on use are followed.

5.7. No EEL value is set at this time, or has been set previously for 1,5-pentadiamine, 2methyl-, as the level of risk of adverse effects to the environment has been qualitatively assessed as being negligible, with controls in place.

5.8. There are no Workplace Exposure Standard (WES) nor Prescribed Exposure Standard (PES) values currently set for the component in Dytek A amine.

6. Changes to prescribed controls

6.1. The following additional HSNO controls apply to Dytek A amine under section 77A of the Act, as set out in Table 3:

Table 3: Justification for the section 77A additional controls (see Appendix A for the control wordings)

Control	Justification
Use restriction	None of the prescribed controls limit how the substance may be used. Accordingly an additional control should be applied to limit the use of Dytek A amine to industrial sites only.

Assessment of changes to controls

6.2. The change to the prescribed controls in the above section under section 77A of the Act fulfil the legislative criteria.

6.3. This control has been incorporated into the Appendix of this document.

6.4. The applicant was provided an opportunity to comment on the controls as set out in this decision and no concerns were raised.

7. Summary

7.1. After taking into account the prescribed controls and any variations to these controls, it was concluded that the residual level of risk of any potentially significant adverse effects, is negligible.

8. Decision

8.1. Pursuant to section 29 of the Act, I have considered this application for approval under section 28 of the Act. I have considered the effects of this substance throughout its life cycle, the controls that may be imposed on this substance and the likely effects of this substance being unavailable. I have also taken into account the considerations set out in Part 2 of the Act.

8.2. I consider that, with controls in place, the risks to human health and to the environment are negligible, and the benefits associated with the release of this substance will outweigh the adverse effects. Therefore, I consider that Dytek A amine is approved with controls in accordance with section 29 of the Act and clause 26 of the Hazardous Substances and New Organisms (Methodology) Order 1998.

Dr Fiona Thomson-Carter	**Date: 05 November 2018**
General Manager, HSNO, EPA	

Appendix: Controls applying to Dytek A amine

EPA Controls

Control code	EPA Notice	Control description
LAB	EPA Labelling Notice 2017	Requirements for labelling of hazardous substances
PKG	EPA Packaging Notice 2017	Requirements for packaging of hazardous substances
SDS	EPA Safety Data Sheet Notice 2017	Requirements for safety data sheets for hazardous substances
DIS	EPA Disposal Notice 2017	Requirements for disposal of hazardous substances
HPC-1	EPA Hazardous Property Controls Notice 2017 Part 1	Hazardous Property Controls preliminary provisions
HPC-2	EPA Hazardous Property Controls Notice 2017 Part 2	Requirements for labelling of hazardous substances
HPC-3	EPA Hazardous Property Controls Notice 2017 Part 3	Hazardous substances in a place other than a workplace
HPC-4A	EPA Hazardous Property Controls Notice 2017 Part 4A	Site and storage controls for class 9 substances
HPC-4B	EPA Hazardous Property Controls Notice 2017 Part 4B	Use of class 9 substances

HSNO Additional Controls and Modifications to Controls

Control Code	HSNO Act	Control
Use restriction	Section 77A	No person may use this substance for any purpose other than as an ingredient or component in the manufacture of a formulated product in an industrial facility.

HSW Requirements

Note: these requirements are not set for the substance under this approval but apply in their own right under the HSW legislation according to the classification of the substance. They are listed here for information purposes only.

Code	Regulation	Description	Extra information
HSW2-1	Reg 2.1 - 2.4	Workplace labelling of hazardous substance containers	
HSW2-2	Reg 2.5 - 2.10	Signage	
HSW2-3	Reg 2.11	Safety data sheets	
HSW2-4	Reg 2.12 - 12.14	Packaging	
HSW3-1	Reg 3.1	Inventory	
HSW3-2	Reg 3.2 - 3.3	Managing risks associated with hazardous substances	
HSW4-2	Reg 4.5 - 4.6	Information, instruction, training and supervision	
HSW5-1	Reg 5.2 - 5.5	Fire extinguishers	
HSW5-2	Reg 5.6 - 5.13	Emergency response plans	
HSW8-2	Reg 8.3 - 8.4	Requirements for public transportation of class 1 to 5 substances	
HSW10-3	Reg 10.5	Requirement to segregate class 2, 3, and 4 substances	
HSW10-5	Reg 10.8 - 10.20	Requirements to prevent unintended ignition of class 2.1.1, 2.1.2 and 3.1 substances	
HSW10-12	Reg 10.30 - 10.33	Secondary containment for class 3 and 4 pooling substances	
HSW11-1	Part 11	Controls relating to adverse effects of unintended ignition of class 2 and 3.1 substances	

HSW13-1	Reg 13.3 - 13.4	Records of application for class 6 substances	
HSW13-2	Reg 13.7	Duty of PCBU who directs work using class 6, 8.1, 8.2, or 8.3 substances to ensure equipment is appropriate	
HSW13-3	Reg 13.8	Duty of PCBU who directs work using class 6 and 8 substances to ensure personal protective equipment used	
HSW13-5	Reg 13.10	Substances not requiring a certified handler to be secured	
HSW13-7	Reg 13.14 - 13.16	Transportation of certain class 6 and 8 substances	
HSW13-8	Reg 13.17	Prohibition on use of substance in excess of tolerable exposure limit	
HSW13-9	Reg 13.18	Duty of PCBU to ensure prescribed exposure standards for class 6 substances not exceeded	
HSW13-13	Reg 13.26 - 13.29, 13.34 - 13.37	Storage and segregation of certain class 6 or 8 substances	
HSW13-14	Reg 13.30 - 33	Secondary containment requirements for class 6 and 8 pooling substances	
HSW13-15	Reg 13.34, 13.38-13.39	Duty of PCBU to establish hazardous substance location and compliance certificate requirements where certain class 6 or 8 substances present	
HSW13-16	Reg 13.40 - 13.44	Separation of hazardous substance locations holding class 6 and 8 substances	
HSW13-17	Reg 13.45	Additional emergency management requirements for certain class 6 or 8 substances	
HSW16-1	Part 16	Requirements for tank wagons and transportable containers	
HSW17-1	Part 17	Requirements for stationary container systems	