Section 3.3

Hazard Classifications Of 1080 and Formulations Containing 1080

1. Introduction

This section outlines the hazard classifications of 1080 and formulations containing 1080 against the threshold criteria set out in the *Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001* and the classification criteria set out in the Hazardous *Substances (Classification) Regulations 2001*. The approach taken has been to assess the 1080 technical grade active against each of the six hazardous properties and to use this data to classify the formulations by using mixture calculations. Therefore the data provided in this section is on the technical grade active.

Formulations of 1080 that are currently registered by the New Zealand Food Safety Authority Agricultural Compounds and Veterinary Medicines (ACVM) group as vertebrate toxic agents are listed in Table 1 below.

Table 1 | **Registered 1080 formulations**

[Source: ACVM website, http://www.nzfsa.govt.nz/acvm/registers-lists/pesticides/index.htm, accessed 1 August 2006]

ACVM Registration Number	Trade Name	HSNO Approved Substance Name	HSNO Approval Number
V003785	0.04% 1080 Pellets	Pellets containing 0.4 – 0.8 g/kg sodium fluoroacetate	HSR002422
V000825	0.06% 1080 Pellets		
V002829	0.08% 1080 Pellets		
V009015	0.08% 1080 Rodent Pellets		
V004107	0.10% 1080 Feral Cat Bait	Pellets containing 1.0 g/kg sodium fluoroacetate	HSR002423
V002848	0.15% 1080 Pellets	Pellets containing 1.5 – 2.0 g/kg sodium fluoroacetate	HSR002424
V002538	0.2% 1080 Pellets		
V004811	Pestoff Professional 1080 Possum & Rabbit Paste 0.06%	Paste containing 0.6 – 0.8 g/kg sodium fluoroacetate	HSR002420
V004812	Pestoff Professional 1080 Possum Paste 0.08%		
V004918	Pestoff Professional 1080 Possum Paste 0.15%	Paste containing 1.5 g/kg sodium fluoroacetate	HSR002421
V009174	Pestoff Exterminator Paste		
P003660	1.0% 1080 Wasp Paste	Paste containing 10 g/kg sodium fluoroacetate	SR002425
V005377	No Possums 1080 Gel Bait	Gel containing 1.5 g/kg sodium fluoroacetate	HSR002419
V003623	5% 1080 Gel	Gel containing 50 g/kg sodium fluoroacetate	HSR002418
V002554	10% 1080 Gel	Gel containing 100 g/kg sodium fluoroacetate	HSR002426
V002189	1080 Solution	Soluble concentrate containing 200 g/litre sodium fluoroacetate	HSR002427

Note: The active ingredient technical grade 1080, which is imported from the USA for bait formulation in New Zealand, is not registered for use in New Zealand as a pesticide. However, technical grade 1080 is approved under the HSNO Act for use in the manufacture of pesticide products (Approval number HSR002771). Data on technical grade 1080 has been used as the reference point for assessing the hazardous properties of pesticide formulations containing 1080.

2. Summary of Hazard Classifications

Table 2 presents a summary of the HSNO hazard classifications for technical grade 1080 and formulations containing 1080, as assessed by Landcare Research, on behalf of the applicants, AHB and DOC. The classifications differ from the ERMA New Zealand classifications in the following areas:

1. The technical grade active is classified as **9.2B** (ecotoxic in the soil environment), based on more recent studies, with formulations containing >1% 1080 correspondingly being classified as **9.2C** (substances that are harmful in the soil environment). ERMA New Zealand had not made any classifications under soil ecotoxicity (9.2) as relevant data was not available at the time of transfer.

2. Pellets containing 0.4 - 0.8 g/kg 1080 are classified as **9.1C** (substances that are harmful to the aquatic environment). ERMA New Zealand has not classified this substance under subclass 9.1.

3. Other formulations that ERMA New Zealand has classified as class **9.1D** (substances that are slightly harmful to the aquatic environment), has been classified as **9.1C** (substances that are harmful to the aquatic environment).

4. Paste containing 10g/kg 1080 has been classified as **9.4B** (substances that are ecotoxic to terrestrial invertebrates). ERMA New Zealand have classified this formulation as class **9.4C** (substances that are harmful to terrestrial invertebrates).

These differences in classification arise from the consideration of more recent data available to the applicant. It is proposed that these classifications be reviewed during the processing of the reassessment application. In the following table, applicant classifications are indicated in brackets e.g.**[B]**.

Table 2 | **HSNO Hazard Classifications for 1080 and Formulations Containing 1080**

Note: Classifications in square brackets have been made by the applicants (AHB and DOC), and differ from those made by ERMA.

				Class 6 Toxicity								**Class 9 Ecotoxicity**			
Approved Substance	**Min. 1080 content**	**Max. 1080 content**	**Units**	**6.1** Acute Toxicity	**6.3** Skin Irritant	**6.4** Eye Irritant	**6.5** Sensitisation	**6.6** Mutagenicity	**6.7** Carcinogenicity	**6.8** Reproductive/ developmental effects	**6.9** Target organ toxicity	**9.1** Aquatic effects	**9.2** Soil eco-toxicity	**9.3** Terrestrial vertebrate	**9.4** Terrestrial invertebrate
Technical grade sodium fluoroacetate	950	980	g/kg	A	B	A				A	A	A	***[B]***	A	A
Pellets containing 0.4 – 0.8 g/kg sodium fluoroacetate	0.4	0.8	g/kg	C								***[C***]		B	
Pellets containing 1.0 g/kg sodium fluoroacetate	1.0	1.0	g/kg	C						A		D **[C]**		B	
Pellets containing 1.5 – 2.0 g/kg sodium fluoroacetate	1.5	2.0	g/kg	B						A		D **[C]**		A	
Paste containing 0.6 – 0.8 g/kg sodium fluoroacetate	0.6	0.8	g/kg	C								**[C**]		B	
Paste containing 1.5 g/kg sodium fluoroacetate	1.5	1.5	g/kg	B						A		D ***[C]***		A	
Paste containing 10 g/kg sodium fluoroacetate	10	10	g/kg	B						A	B	D ***[C]***	***[C]***	A	C ***[B]***

				Class 6 Toxicity								Class 9 Ecotoxicity			
Approved Substance	**Min. 1080 content**	**Max. 1080 content**	**Units**	**6.1** Acute Toxicity	**6.3** Skin Irritant	**6.4** Eye Irritant	**6.5** Sensitisation	**6.6** Mutagenicity	**6.7** Carcinogenicity	**6.8** Reproductive/ developmental effects	**6.9** Target organ toxicity	**9.1** Aquatic effects	**9.2** Soil eco-toxicity	**9.3** Terrestrial vertebrate	**9.4** Terrestrial invertebrate
Gel containing 1.5 g/kg sodium fluoroacetate	1.5	1.5	g/kg	B			B			A		D		A	
Gel containing 50 g/kg sodium fluoroacetate	50	50	g/kg	A						A	B	D ***[C]***	***[C]***	A	B
Gel containing 100 g/kg sodium fluoroacetate	100	100	g/kg	A	B	A				A	A	A	***[C***]	A	B
Soluble concentrate containing 200 g/litre sodium fluoroacetate	200	200	g/litre	A	B	A				A	A	A	***[C]***	A	B

3. Hazard Classification

The six hazardous properties that must be considered under HSNO are:

- explosiveness
- flammability
- oxidising capacity
- corrosiveness
- toxicity
- ecotoxicity

The relevant criteria for classification are set out in the *Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001* and the *Hazardous Substances (Classification) Regulations 2001.*

The approach taken in this application has been to assess the properties of the technical grade 1080 active against each of the six hazardous properties and to use these classifications to classify the formulated products.

3.1 Properties of the Components of 1080 Formulations

HSNO defines “substances” as including both pure components and mixtures or formulations containing a number of individual components. In the absence of data on the formulated products, each substance must be therefore be classified by considering the hazardous properties of all its components.

Composition data on 1080 formulations are proprietary information and the identity and concentration of many of the components are confidential. The hazardous properties of components other than 1080 have been reviewed and assessed independently and this information is presented in Appendix B of the Application (confidential to ERMA). All other components of the formulations currently used are either themselves non-hazardous or do not contribute further to the overall hazard classification of the formulation. Thus the hazard classifications of the formulations containing 1080 are based on the concentration of 1080 in the formulation.

The only exception to this is the gel containing 1.5 g/kg sodium fluoroacetate, which has been classified as a contact sensitiser (6.5B), based on one of the components in the formulation.

3.2 Physical Properties of the technical grade 1080 and 1080 formulations

Explosiveness **Not classified as explosive under HSNO**

The chemical structure of 1080 (FCH2CO2Na) suggests that it is unlikely to have explosive properties, and there is no published evidence to indicate that 1080 formulations are capable of sudden expansion owing to a release of internal energy, including the ability to generate deflagration or pyrotechnic effects. None of the Material Safety Datasheets (MSDS) relating to 1080 formulations in New Zealand indicate an explosive hazard.

Flammability **Not classified as flammable under HSNO**

1080 is a colourless hygroscopic powder. Material Safety Datasheets (MSDSs) for 1080 formulations produced by Animal Control Products (2002) indicate that 1080 decomposes at 200°C, becoming unstable at 110°C. The MSDSs also indicate that 1080 formulations are stable and non-reactive under normal storage conditions. Based on the conclusion that 1080 itself is not flammable and that none of the formulations contain other components that trigger either classification as a flammable liquid (the soluble concentrate) or as a flammable solid, the formulations are not classified as flammable under HSNO.

Oxidising capacity **Not classified as an oxidiser under HSNO**

The chemical structure of 1080 suggests that it has no free oxygen groups that could release chemical energy and impart an ability to promote fire.

The MSDS also indicate that 1080 formulations are stable and non-reactive under normal storage conditions. On this basis, it is likely that 1080 and formulations containing 1080 do not meet any of the HSNO classification criteria for substances with oxidising properties.

Corrosiveness **Not classified as corrosive under HSNO**

No evidence was found to suggest that 1080 formulations are corrosive to metals. The effects on dermal or ocular tissue (or otherwise) of aqueous or liquid formulations containing 1080 are discussed when assessing classification under classes 6.3 and 6.4.

Toxicity **1080 triggers threshold criteria for toxicity (Class 6)**

Ecotoxicity **1080 triggers threshold criteria for ecotoxicity (Class 9)**

3.3 Summary

1080 and formulations containing 1080 covered by this application for reassessment are not classified as explosive, flammable, oxidising, or corrosive under HSNO. Sections 4 and 5 of this document deal with their toxic and ecotoxic properties, and provide a classification against each Subclass for the various formulations.

4. **Toxic Properties: Class 6**

4.1 **Subclass 6.1 Acute Toxicity**

Classification of 1080 active:	
LD_{50} value (oral): 0.06 mg/kg bw (Chenoweth, 1949)	6.1A (acutely toxic)
LD_{50} value (dermal): 277 mg/kg bw (Fagerstone et al, 1994)	6.1C (acutely toxic)
LC_{50} value (inhalation):	no data
Overall classification assigned to 1080 active:	**6.1A**

4.1.1. Summary of data supporting classification

The highest reported susceptibility of a mammal species was used for this classification: the acute oral LD_{50} for dogs (*Canis familiaris*) of 0.06 mg/kg bw (Chenoweth, 1949). Estimates of acute oral toxicity in humans range from 0.71 to 5.0 mg/kg bw (Fairchild, 1977) and from 2.0 to 10.0 mg/kg bw (Chenoweth, 1949).

The acute dermal LD_{50} value of 277 mg/kg bw reported for male rabbits (Fagerstone et al, 1994) is used for classification purposes, as it is the lowest reported dermal toxicity value in a mammalian species, derived from an acceptable test methodology (USEPA OPP Code 81-2).

No acute inhalation toxicity values for 1080 were found.

The overall acute toxicity classification of 6.1A was assigned for the 1080 technical grade active.

4.1.2. Oral toxicity

The extremely toxic nature of 1080 when ingested or injected is well recognised and there is an extensive database on the acute oral toxicity of 1080 (e.g. Atzert, 1971; Rammell and Fleming, 1978; Eisler, 1995). Whilst 1080 is a broad-spectrum toxin, there are some marked differences in susceptibility between, and even within, species. However, mammals are recognised as being relatively the most susceptible organisms to 1080 through the oral route (see Subclass 9.3 – Terrestrial vertebrate ecotoxicity). Cases of acute human poisoning have been reported outside of New Zealand (eg Brockmann, 1955; Harrison, 1952; Trabes, 1983; Chi et al, 1996 and 1999; Robinson et al. 2002) and have generally been either accidental ingestion of a pest control product by children, or deliberate ingestion by adults.

4.1.3. Dermal toxicity

It is reported that 1080 can be absorbed through the gastrointestinal and respiratory tracts, open wounds, and mucous membranes, but it is less readily absorbed through intact skin (Atzert 1971). As part of regulatory toxicology studies completed in the USA, acute dermal toxicity of 1080 in rabbits was assessed. In this test, five male and five female rabbits for each of four dose levels were treated dermally with 1080 paste. The estimated dermal LD_{50} was 324 mg/kg bw for females and 277 mg/kg bw for males (Fagerstone et al. 1994).

4.1.4. Inhalation toxicity

1080 powder or solution is not volatile but could become airborne as dust, fine particles or mist. While there were no values found for inhalation toxicity of 1080 (eg. LC_{50} values) it is assumed that the high acute oral toxicity reflects the likely inhalation toxicity. A published account of a person who accidentally inhaled 1080 powder (Williams 1948) notes " ..a tart, sourish taste……

followed almost immediately by a tingling sensation around the corners of the mouth and in the nasal passages……soon the entire face had become numb, and the tingling sensation was rapidly entering the arms and legs. This was followed by spasmodic contractions of the voluntary muscles, gradual loss of speech, and within 2 and 1/2 hours after inhaling the powder as noted above, unconsciousness. No actual pain was noted during the entire onset".

4.1.5. Determination of acute toxicity classification for mixtures containing 1080

The technical grade active has an overall acute toxicity classification of 6.1A, based on the oral LD_{50} for dogs of 0.06 mg/kg bw (Chenoweth, 1949). The 1080 formulations were assigned classifications with reference to mixtures with components without any useable information, using the calculation:LD_{50} mixture= 0.06 × 100/concentration 1080 in mixture

4.2 **Subclass 6.3 Skin Irritation**

Classification of 1080 active:	**6.3B**

4.2.1. Summary of data supporting classification

No Draize score or skin irritancy data for active ingredient 1080 was found. However, primary dermal irritation was assessed in six albino rabbits treated dermally with 1% 1080 (Fagerstone et al. 1994), by keeping the chemical in contact with the skin for 4 hours. 1080 did not cause erythema and edema was absent to slight at 5 hours but absent thereafter. 1080 was classified in this study as a Category IV dermal irritant (having "mild or slight dermal irritation at 72 hours"), using a scale adopted from the U.S. Code of Federal Regulations 40 CFR 156.10 (h)(1)(i), July 1, 1991. On the basis of this result, derived from an acceptable test methodology (USEPA OPP Code 81-5), technical 1080 is classified as Category 6.3B – a substance mildly irritating to the skin.

4.2.2. Determination of classification for mixtures containing 1080

The concentrations of components that are classified as skin irritants are used to determine the skin irritation classification of the mixture as either a corrosive or irritant effect. If the skin irritating component of a substance as a mixture is less than 1% (w/w) solids/liquids, then it is below the threshold for skin irritating effects. The classification of 6.3B skin is assigned to the soluble concentrate containing 200 g/litre 1080, the gel containing 100 g/kg 1080 as both these contained ≥ 10% of technical 1080 which was classified 6.3B.

4.3 **Subclass 6.4 Eye Irritation**

Classification of 1080 active:	**6.4A**

4.3.1. Summary of data supporting classification

No Draize score or eye irritancy data for active ingredient 1080 was found. Primary eye irritation was assessed in six albino rabbits were treated with a 1% 1080 solution (Fagerstone et al. 1994) which was placed in the conjunctival sac of the eye, and ocular responses were recorded for up to 3 days. 1080 caused no corneal opacity or iritis, and slight conjunctival irritation. 1080 was classified in this study as a Category III ocular irritant (having "corneal involvement of irritation clearing in 7 days or less"), using a scale adopted from PR NOTICE 81-3, Notice to Manufacturers, Formulators, Distributors and Registrants of Pesticides – Label Improvement

Program: Change in Test Methods for and Categorization of Eye Irritation, dated 9/29/81. On the basis of this result, derived from an acceptable test methodology (USEPA OPP Code 81-4), 1080 is classified as Category 6.4A – a substance irritating to the eye.

4.3.2. Determination of classification for mixtures containing 1080

The concentrations of components that are classified as eye irritants are used to determine the eye irritation classification of the mixture as either a corrosive or irritant effect. If the eye irritating component of a substance as a mixture is less than 1% (w/w) solids/liquids, then it is below the threshold for eye irritating effects. The classification of 6.4A was assigned to the technical 1080 and hence also applied to those mixtures with ≥ 10% 1080: the soluble concentrate containing 200 g/litre 1080 and the gel containing 100 g/kg 1080.

4.4 **Subclass 6.5 Sensitisation**

Classification of 1080 active:	**not assigned**

4.4.1. Summary of data supporting classification

No measured (direct or indirect) data regarding the contact or respiratory sensitising properties of 1080 were found. The absence of measured sensitisation data could not be addressed by a weight of evidence approach, as no relevant animal studies or appropriate evidence in humans were found in literature searches. The requirement for this dataset for 1080 in the United States was waived, due to very high acute toxicity of the compound, and the limited application of 1080 in livestock protection collars (Fagerstone et al 1994). However, the uses of 1080 in New Zealand (i.e. a variety of bait formulations containing different concentrations of active) are substantially different to those in the United States (a solution used in livestock protection collars).

Some formulations of 1080 used in New Zealand have potential for occupational human exposure (e.g. Fisher et al. 2002), although it is currently not understood whether this is via dermal (e.g. solutions), inhalation (e.g. dust from pellet baits) or other routes. Classification of 1080 in subclasses 6.1 (based on high acute oral toxicity and dermal toxicity) and 6.3 (skin) may preclude the need for data in this subclass, because the relevant controls would also be likely to protect against sensitisation reactions through dermal or inhalation exposure. Since there is no measured or indirect data on the substances for the sensitisation subclass, a definitive hazard classification cannot be assigned here.

The technical grade active is not classified as a sensitiser therefore the 1080 formulations are not classified as sensitisers.

It should be noted however, that ERMA New Zealand have classified the gel containing 1.5 g/kg 1080 as a class 6.5B contact sensitiser, based on one of the components in this formulation.

4.5 **Subclass 6.6 Mutagenicity**

Classification of 1080 active:	**not assigned**

4.5.1. Summary of data supporting classification

Results of three different, complementary tests indicate that 1080 is not mutagenic (Eason et al. 1999). In the Ames assay (bacterial gene mutation assay) no mutagenicity was observed at

sodium monofluoroacetate doses of 10, 31.6, 100, 316 and 1000 μg/plate (MPI Research 1998). In the mouse lymphoma assay (mammalian gene mutation assay) no mutagenicity was observed at sodium monofluoroacetate doses of 5 to 5000 μg/mL (MPI Research 1998a). In the mouse micronucleus assay (bone marrow assay to detect chromosome anomalies) mice were given oral 1080 doses of 0.75, 1.5, 3.0, 6.0 and 7.5 mg/kg with no mutagenicity (MPI Research 1998b). All of this data was derived from acceptable test methodologies, as specified in Section 7.4; (*Salmonella typhimurium* reverse mutation assay OECD code 471; Detection of gene mutations in somatic cells in culture OECD code 476; In vivo mammalian cytogenetic test bone marrow micronucleus assay OECD code 474).

No mutagenicity was observed at any dose level of 1080 in any of the above tests, accordingly no mutagenic classification was assigned to the technical grade active or any 1080 formulation for this subclass.

4.6 **Subclass 6.7 Carcinogenicity**

Classification of 1080 active:	**not assigned**

4.6.1 Summary of data supporting classification

No measured (direct or indirect) data using the acceptable test methodologies for testing the carcinogenicity threshold were found for 1080. No scientific publications investigating a causal relationship between exposure to the agent and human or animal cancer were found. In the absence of measured data, and as per Section 8.5 (i)(x) of the User Guide, genetic events are central in the overall process of cancer development. Because the results of three different, complementary tests indicate that 1080 is not mutagenic (Eason et al. 1999), 1080 is therefore not anticipated to cause cancer and no classifications were assigned in Subclass 6.7.

4.7 **Subclass 6.8 Reproductive/Developmental Effects**

Classification of 1080 active:	**6.8A**

4.7.1. Summary of data supporting classification

Effects of 1080 on testes as a target organ have been reported in a range of studies, including two (Wolfe 1988; Eason and Turck 2002) derived from an acceptable test methodology (OECD Test Guideline 408 repeated dose 90-day oral toxicity study in rodent species). Other studies indicate that 1080 also has teratogenic effects, including a relatively recent laboratory rodent study reported by Eason et al. (1999) which meets the OPPTS guideline for a prenatal developmental toxicity study (PRRTS Code 870.3700).

Given this combined information, technical grade (active) 1080, and formulations containing ≥ 1% 1080 were assigned the classification of 6.8A – a substance that is a known or presumed human reproductive or developmental toxicant.

4.7.2. Teratogenicity / Developmental toxicity

Early reports indicated that relatively high doses of fluoroacetate could cause teratogenicity in rats (Hicks 1952; De Meyer and Plaen 1964), although no teratogenicity was found by Spielmann et al. (1973). A more recent study has confirmed that 1080 caused developmental defects in rats when pregnant females were exposed to relatively high doses (0.33 and 0.75 mg/kg) on a daily basis during the period of organogenesis (from days 6 through to 17 of

gestation) (Eason et al. 1999). In the pilot dose-ranging study preceding the main study by Eason et al. (1999), 5 female rats per treatment group were dosed orally with 1080 in solution at 0, 0.05, 0.1, 0.5 or 1.0 mg/kg/day from Day 6 through to Day 17 of gestation (inclusive). All females were euthanased on Day 20, one day before complete gestation was expected. No effects on uterine parameters (gravid uterine weight, number of implantations, resorptions and live and dead foetuses) were observed at any dose. Maternal toxicity (weight loss and 60% mortality) and decreased litter size was observed at 1.0 mg/kg/day. The NOEL from the pilot study, based on gross pathological examination of the female rats was 0.5 mg/kg/day; however the foetuses were not examined.

In the main study (Eason et al. 1999), 26 female rats per treatment group were dosed orally with 1080 solution at 0, 0.1, 0.33 or 0.75 mg/kg/day from Day 6 through to Day 17 of gestation and euthanased on Day 20. No clinical symptoms of maternal toxicity were observed at any dose, although decreased maternal and foetal bodyweight was observed in the 0.75 mg/kg/day treatment group. No external or visceral soft tissue abnormalities were observed in foetuses at any dose, however skeletal abnormalities were observed in the 0.33 and 0.75 mg/kg/day groups. These included abnormal development of the forelimbs, characterised by bent scapula, humerus, and radius or ulna, observed in 24%, 12% and 8% of litters respectively. These changes were mild, but treatment-related and classified as irreversible alterations of skeletal development (malformations). Bent ribs were observed in 20% and 52% of litters at 0.33 mg/kg/day and 0.75 mg/kg/day respectively. Unossified sternebrae were also observed in 72% of litters at 0.75 mg/kg/day. These latter two developmental abnormalities are classified as variations rather than malformations because they are considered to be reversible, and may potentially be due to maternal stress rather than direct toxicity to the foetus. In summary, teratogenic effects of 1080 occurred at 0.75 mg/kg/day dose and the developmental no-observable-effects-level (NOEL) was 0.1 mg/kg/day (Eason et al. 1999).

A New Zealand study simulated potentially realistic sublethal exposure of non-target livestock (sheep) to 1080 as the result of its use as a vertebrate pesticide, where pregnant ewes were administered a single (0.25 mg/kg) or multiple oral doses (0.05 mg/kg over 3 consecutive days) of a 1080 cereal pellet i.e. high sublethal doses. In those ewes that survived these doses there were no differences in growth rates between lambs from dosed and undosed pregnant ewes (O'Connor et al. 1999).

4.7.4. Effects on reproductive tissues (testes as a target organ)

A number of target organs are subject to 1080 toxicity, and these are covered in in the following subclass. However, sodium fluoroacetate is recognised as a "male reproductive toxicant" because effects on testes have been described in mammals (e.g. Mazzanti 1965; Sullivan et al. 1979; Hornshaw et al.1986; Wolfe 1988; Al-Juburi et al. 1989; Shinoda et al. 2000; Eason & Turck 2002), at least one species of bird (Balcomb et al. 1983) and one species of reptile (Twigg et al. 1988). Accordingly, this aspect of 1080 toxicity was included under Subclass 6.8.

In an unpublished 90-day study (Wolfe, 1988), sodium fluoroacetate was administered by oral gavage to Sprague-Dawley rats (20 animals/sex/group) at doses of 0, 0.05, 0.20 and 0.50 mg/kg/day, for13 weeks. No treatment-related findings were noted in survival, clinical observations, mean body weights, body weight gains, total food consumption, opthalmological examinations, or haematology and clinical chemistry, except for fluorocitrate results. Treatment-related findings were noted in absolute and/or relative organ weights of the testes/epididymides. Significant decreases in absolute and relative testes/epididymides weights in Groups 3 and 4 males were accompanied by corresponding findings in gross and microscopic pathology. At

necropsy, testes/epididymides were noted as small. Microscopic examination of the tissues revealed compound-related findings in the testes and epididymides and the mid and high-dose rats. Testicular changes consisted of bilateral hypospermatogensis with fusion bodies in the seminiferous tubules. Changes in the epididymides consisted of immature/abnormal sperm forms and hypospermatogenesis with reduced numbers of sperm forms in the epididymal ducts. Testes and epididymides from low-dose rats showed no evidence of compound-related effects. The findings of this study indicated that the NOEL for sodium fluoroacetate in rat was 0.05 mg/kg/day.

In the most recently completed regulatory toxicology study of 1080 (Eason and Turck 2002), groups of Sprague-Dawley rats received sodium fluoroacetate at 0.025, 0.075, and 0.25 mg/kg by oral gavage once daily for 90 days and were then euthanased. The control and 0.25 mg/kg/day groups included additional rats of each sex that were treated for 90 days, then maintained without treatment for a further 56-day recovery period. Microscopic changes were restricted to the testes and the heart, and were seen only in males dosed with 1080 at 0.25 mg/kg/day and included severe hypospermia in the epididymides, severe degeneration of the seminiferous tubules of the testes, and cardiomyopathy. Sperm evaluation indicated severe decreases in all three sperm parameters evaluated (concentration, % motile, and % abnormal) at 0.25 mg/kg/day and did not return to normal after 56 days cessation of exposure. There were no microscopic changes or 1080-related effects on sperm parameters at 0.025 and 0.075 mg/kg/day. The NOEL for rats administered 1080 via oral gavage for 90 days was 0.075 mg/kg/day. The lowest observable effects level (LOEL) dose was 0.25 mg/kg/day. There is some suggestion that the effects of 1080 on testes may be time-defined or reversible (Sullivan et al. 1977), although there have been no studies with a recovery period to adequately investigate this. Also there have been no multigenerational studies conducted to evaluate the extent to which sublethal 1080 exposure affects reproductive performance and whether there is recovery from these effects over time.

In contrast to the above studies reporting effects on testes, no treatment-related findings were noted in the absolute organ weights of ovaries in Sprague-Dawley rats (20 animals/sex/group) administered sodium fluoroacetate by oral gavage at doses of 0, 0.05, 0.20 and 0.50 mg/kg/day, for 13 weeks (Wolfe 1988). No significant changes in organ weights were noted in ovaries of female rats receiving sodium fluoroacetate at 0.025, 0.075 and 0.25 mg/kg by oral gavage daily for 90 days (Eason & Turck 2002).

4.7.5. Determination of classification for mixtures containing 1080

The hazard cut-off level for this classification is ≥0.1% w/w of an active ingredient in a mixture; the 6.8A classification was assigned to formulations with ≥0.1% w/w 1080 active (i.e., all formulations except for the paste containing 0.6 - 0.8 g/kg 1080 and pellets containing 0.4 - 0.8 g/kg 1080).

4.8 **Subclass 6.9 Target Organ Systemic Toxicant**

Classification of 1080 active:	**6.9A**

4.8.1. Summary of data supporting classification

While testes have been identified as a target organ in animal studies, this specific data has been considered in Subclass 6.8 Reproductive / Developmental Effects. From animal studies, the heart appears also to be a target organ of fluoroacetate, and reported effects on the heart

are the main basis for the classification in this 6.9 subclass. On the basis of evidence from earlier studies, and then the relatively low (repeated) exposure concentrations represented by NOEL / LOEL data from more recent rat studies (Wolfe 1988; Eason and Turck 2002) which were derived from an acceptable test methodology (OECD Test Guideline 408 repeated dose 90-day oral toxicity study in rodent species) the classification of 6.9A was assigned, using definition (b) "….for which data indicate to an expert evidence of a significant adverse biological effect on the function or morphology of an organ……that are produced at low exposure concentrations and are relevance to human health".

4.8.2. Heart as a target organ

That single or repeated sublethal exposures to fluoroacetate can have toxic effects on the heart has been recognised for some time (e.g. Steyn 1934; Quin and Clark 1947; Hicks 1952). In general, the action of fluoroacetate on the heart is to decrease the metabolic energy available in heart muscle, which affects the conduction system controlling the rate and strength of heart beats (e.g. Chenoweth and Gilman 1947). A number of *in vitro* studies have described general effects of fluoroacetate on heart tissue from different species; biochemical e.g. citrate accumulation (e.g. Dietrich and Shapiro 1956), depletion of ATP and depression of respiration (Bowman 1964; Williamson et al. 1964; Corsi and Granata 1967; Godoy and Villarruel 1974; Buffa et al. 1979), physiological e.g. intropic effects and arrythmia (Quin and Clark 1947; Ando 1966; Noguchi et al 1966; Dunn 1968; Cerutti and Peters 1969; Korth et al 1978; Burande et al. 1983) and histological e.g. mitochondrial swelling (Noguchi et al 1966; Barasa et al. 1973).

A number of *in vivo* studies have also reported effects on the heart consistent with those found in vitro (e.g. Bosakowski & Levin 1986; Bowman 1964; Cole et al. 1955; Stewart et al 1969; Kirzon et al. 1970). Species differences in organs most affected by lethal doses of fluoroacetate have frequently been noted in the literature. In general, during lethal 1080 poisoning, herbivores experience cardiac failure (e.g. Frick 1946; Jensen 1948; Meikle et al 1996), whereas carnivores experience central nervous system disturbances and convulsions then die of respiratory failure (Egekeze & Oehme 1979). 1080-induced changes in citrate content of the heart are more pronounced than in any other organs in sheep (Annison et al. 1960; Schultz et al. 1982). In herbivores especially, sublethal doses of fluoroacetate have been shown to cause damage to heart muscle. Mild cardiac histopathology in sheep at doses of 0.055 mg/kg/day has been reported, but the duration of treatment was not specified (Whittem & Murray 1963). Replacement fibrosis in the myocardium of African antelope species and goats dosed with extracts of the fluoroacetate-bearing plant gifblaar (*Dichapetalum cymosum*) became evident in animals that survived for 2 or more days (Basson et al 1982). Schultz et al. (1982) dosed sheep with fluoroacetate via stomach tube at rates of 0.05–1.0 mg/kg/day. Microscopic lesions in the hearts of acutely poisoned sheep included degeneration and necrosis of individual or small groups of myocardial fibers, whilst in sublethally and chronically poisoned sheep the multifocal myocardial lesions were more widespread and in various stages of development or resolution. Following a single sublethal dose of 1080 to sheep (0.25 – 0.30 mg/kg, a high sublethal dose), 50 of sheep killed two weeks later exhibited focal myocardial lesions in the left and right ventricular free walls. These lesions were characterised by multiple scattered foci of necrosis. Sheep killed more than 2 years after the dose showed scattered foci of fibrous tissue in cardiac muscle, which may have represented scarring resulting from toxin-induced damage (Wickstrom et al. 1997).

In an unpublished 90-day study (Wolfe, 1988), sodium fluoroacetate was administered by oral gavage to Sprague-Dawley rats (20 animals/sex/group) at doses of 0, 0.05, 0.20 and 0.50 mg/kg/day, for 13 weeks. Treatment-related findings were noted, where absolute and relative

heart weights were significantly increased in Group 4 males and Group 3 and 4 females. The no-observed-effect-level (NOEL) for sodium fluoroacetate, when given orally to Sprague-Dawley rats for 13 weeks, was 0.05 mg/kg/day (Wolfe 1988). In a similar study except for the inclusion of a recovery period, the NOEL for rats administered 1080 via oral gavage for 90 days was 0.075 mg/kg/day, and the lowest observable effects level (LOEL) dose was 0.25 mg/kg/day (Eason and Turck 2002). There were 1080-related changes in heart weights of male and female rats at 0.25 mg/kg/day after 90 days, where the heart to body weight ratio was significantly increased when compared to controls. In male rats this effect was still evident after 56 days without 1080 exposure (Eason & Turck 2002).

4.8.3. Other target organs

In groups of Sprague-Dawley rats receiving sodium fluoroacetate at 0.025, 0.075 and 0.25 mg/kg by oral gavage daily for 90, no significant changes in kidney or liver weight were measured and no microscopic changes were seen in kidney or liver tissue (Eason and Turck 2002). In male and female Sprague-Dawley rats aged 43 days, which received 0.05, 0.20 and 0.50 mg/kg sodium fluoroacetate per day for 13 weeks, no treatment-related effects were noted in kidney/liver histopathology or kidney/liver weight (Wolfe 1988).

In groups of male Sprague-Dawley rats receiving sodium fluoroacetate at 0.025, 0.075 and 0.25 mg/kg by oral gavage daily for 90 days, a slight increase in brain weight was noted in the 0.075 mg/kg group at terminal sacrifice (Eason and Turck 2002) although this was not mentioned as a treatment-related effect by the authors. In male and female Sprague-Dawley rats aged 43 days, which received 0.05, 0.20 and 0.50 mg/kg sodium fluoroacetate per day for 13 weeks, no treatment-related effects were noted in brain histopathology or weight of brain and stem (Wolfe 1988). Absolute spleen weights were significantly decreased in male rats receiving 1080 dose of 0.50 mg/kg/day for 13 weeks (Wolfe 1988). No treatment-related findings were noted in the absolute organ weights of adrenal glands in Sprague-Dawley rats (20 animals/sex/group) administered sodium fluoroacetate by oral gavage to at doses of 0, 0.05, 0.20 and 0.50 mg/kg/day, for 13 weeks (Wolfe 1988). No significant changes in organ weights of adrenals were noted in female and male rats (Eason and Turck 2002).

4.8.4. Determination of classification for mixtures containing 1080

Substances as a mixture with >10% technical 1080 were classified as 6.9A, and those with >1.0% and <10% 1080 were classified as 6.9B.

5.0 **Ecotoxic Properties: Class 9**

5.1 **Subclass 9.1 Aquatic Ecotoxicity**

Classification of 1080 active:	**9.1A**

5.1.1. Summary of data supporting classification

Acute fish toxicity data derived using an acceptable test methodology (USEPA OP Code 72-1) indicates a lowest estimate 96-hour LC_{50} value as 39 mg/L (lower confidence interval of lowest LC_{50} value calculated for rainbow trout (*Oncorhynchus mykiss*)). Acute toxicity tests in the freshwater invertebrate *Daphnia magnia*, derived from an acceptable test methodology (USEPA OP Code 72-2), indicates a 48-hour EC_{50} of 350 mg/L. Acute algal (*Selenastrum capricornutum*) toxicity data indicates an EC_{50} – 72 hour value of 0.012-0.12 mg/L.

On a weight of evidence basis, sodium fluoroacetate is considered to be rapidly degraded in natural aquatic environments, due to both dilution/dispersion and biotic degradation, and not considered to have potential for bioaccumulation in natural water. The EC_{50} value for the most sensitive aquatic organism, algae, indicates a classification for active ingredient 1080 of 9.1A – a substance that is very ecotoxic in the aquatic environment.

5.1.2. Acute and chronic aquatic toxicity - fish

Historical data indicate that in comparison to mammals, fish are relatively resistant to 1080. Fingerling bream and bass (species unidentified) survived indefinitely, without any signs of toxicity, in water containing 370 ppm 1080 (King & Penfound 1946). In New Zealand, fingerling trout (species not identified) were subjected to 1080 concentrations of 500 and 1000 ppm without any visible effect on the fish, and in a separate study rainbow trout (species not identified) were maintained in 580 ppm 1080 for 24 hours with no ill-effects (Batcheler 1978). Force-feeding pellets containing a total of about 4 mg of 1080 (two fingerling trout and five adult trout) or about 8 mg of 1080 (two adult trout) also had no visible effect (Rammell & Fleming 1978). The LD_{50} of 1080 after intraperitoneal injection to rainbow trout was approximately 500 mg/kg (Bauermeister et al. 1977). However none of these earlier studies met acceptable test methodologies for the purposes of this hazard classification.

During 1993, acute aquatic toxicity tests were completed in the USA. Two aquatic toxicity tests were done in fish, both meeting then US EPA Guideline Number 72-1 (GDLN now equivalent USEPA OPP code) (Fagerstone et al. 1994). The first estimated the acute toxicity of 1080 to bluegill sunfish (*Lepomis macrochirus)* under static renewal test conditions. Following the termination of the test at 96 hours, no mortality or sub-lethal effects were observed at any concentration tested; therefore the NOEC (the no-observed-effect concentration) was determined to be 970 mg/L (ppm), the highest concentration tested. Based on the results of this study and criteria established by the US Environmental Protection Agency, 1080 would be classified as practically non-toxic to bluegill sunfish.

The second test, on rainbow trout (*Oncorhynchus mykiss*), used the same test conditions as the bluegill sunfish studies. Following termination of the test at 96 hours, mortality ranged from 50% to 90% in four treatment levels ranging from 39 to 170 mg/L. In addition, mortality was 10% at the 23 mg/L treatment level, and sub-lethal effects were observed at levels over 23 mg/L. Sublethal effects were observed among surviving fish exposed to levels over 23 mg/L. No mortality or sub-lethal effects were observed in fish exposed to the 13 mg/L level. The 96-hour

LC_{50} value for rainbow trout was calculated to be 54 mg/L with 95% confidence intervals of 39-74 mg/L. The NOEC was 13 mg/L, which the US EPA classifies as slightly toxic to rainbow trout. No studies meeting the acceptable test methodologies for chronic toxicity to fish of 1080 were found.

5.1.3. Acute and chronic aquatic toxicity - invertebrates

An early experiment reported that fourth-instar mosquito larvae (*Anopheles quadrimaculatus*) were comparatively sensitive to 1080 (Deonier et al. 1946). In 48 hours, sodium fluoroacetate concentrations in acetone-water suspensions of 0.025 mg/L were fatal to 15%, 0.5 mg/L to 40%, and 0.1 mg/L to 65% of fourth-instar larvae. However this study did not allow calculations of LC_{50} or NOEC values, and was not considered to meet acceptable test methodologies for the purposes of this hazard assessment. During 1993, acute aquatic toxicity tests were completed in the USA. An aquatic toxicity test was done with *Daphnia magna*, meeting then US EPA Guideline Number 72-2 (GDLN now equivalent USEPA OPP code) (Fagerstone et al. 1994). This test estimated the acute toxicity (EC_{50}) of 1080 to *Daphnia magna*. The EC_{50} was defined as the concentration in water that immobilises 50% of the exposed daphnids. Following the termination of the test at 48 hours, 70 to 100% immobilisation was observed among daphnids exposed to levels of 350 to 980 mg/L respectively. Immobilisation of 5% was observed among daphnids exposed to 220 mg/L. Sub-lethal effects were observed among all the mobile daphnids exposed to 220–590 mg/L, but were not observed among those exposed to 130 mg/L. The 48-hour EC_{50} value for daphnids exposed to 1080 was calculated to be 350 mg/L and the NOEC was determined to be 130 mg/L, making 1080 practically non-toxic to *Daphnia magna* by US EPA classification standards (Fagerstone et al. 1994). No studies meeting the acceptable test methodologies for chronic toxicity of 1080 to aquatic invertebrates were found.

5.1.4. Acute and chronic aquatic toxicity – plants and algae

Gallon et al. (1977) reported that 1 mM sodium fluoroacetate did not affect photosynthetic oxygen-evolution by blue-green algae *Gloeocapsa* spp., but did inhibit acetylene reduction under aerobic conditions. The effects of sodium fluoroacetate upon soil algae *Chlorella* and *Chlamydomonas* and on the growth of a duck weed (*Spirodela oligorrhiza*) were investigated (Bong et al 1979). The growth of the algae were unaffected by sodium fluoroacetate concentrations of up to 20 mM but the growth of the duck weed, measured by increase in frond numbers, was inhibited by 73% in the presence of 5 μM sodium fluoroacetate, whilst higher concentrations caused chlorosis and suppressed growth. In a subsequent investigation, the toxic effects of fluoroacetate upon the growth of three different species of duckweed (*Lemma minor, Spirodela oligorrhiza* and *S. polyrrhiza*) were compared (Bong et al. 1980). *S. polyrrhiza* was the most sensitive to sodium fluoroacetate within concentrations of 1-100 μM, and growth was totally inhibited in this species by 0.5 mM sodium fluoroacetate, whereas total inhibition of *S. oligorrhiza* and *L. minor* required 1mM sodium fluoroacetate. It was concluded that duckweeds were sensitive to fluoroacetate, in contrast to other plant species (Bong et al. 1980). A toxicity test with fluoroacetate and the blue-green alga *Microcystis aeruginosa* revealed a toxicity threshold value of 0.4 μg/L (Bringmann and Kuhn 1976 cited in Berends et al. 1999). The toxicity of sodium fluoroacetate to aquatic algae species *Selenastrum capricornutum, S. subspicatus* and *Chorella vulgaris* was determined (Berends et al. 1999). Based on measurements of growth rates of each species, EC_{50} – 72 hour values for sodium fluoroacetate were estimated as 0.012 – 0.12 mg/L for *S. capricornatum* and *S. subspicatus*, and <124 mg/L for *C. vulgaris*. Although the authors (Berends et al. 1999) state “it was not the purpose of the experiments to determine accurate NOEC or EC50 values”, so the study described probably

does not meet the criteria for acceptable test methodologies. However, this and previously cited studies can be included in a weight of evidence consideration of classification in subclass 9.1.

5.1.5. Degradation in water

No DT_{50} value (half-life in water) for sodium fluoroacetate was found. Laboratory studies have shown that 1080 is biodegraded in the presence of aquatic plants and micro-organisms. The rate of degradation was measured in stream water in aquaria in the presence of the endemic aquatic plant *Myriophyllum triphyllum*, which had a significant effect on 1080 degradation rate, with concentrations decreasing below detectable levels in 1 day at 23°C and 3 days at 7°C (Oglivie et al 1995).

In a similar study, concentration of fluoroacetate remained relatively constant in deionised (sterile) water at 11° and 21°C but decreased with time in stream water. Degradation was more rapid in the stream water at 21 than at 11øC and the presence of the aquatic plant *Elodea canadensis* was considered to play a mediating role in the degradation of sodium fluoroacetate (Ogilvie et al. 1996). Fluorocitrate (the active metabolite of 1080) has been detected in aquaria spiked with 1080, and its disappearance paralleled that of 1080 (Booth et al. 1999). These studies indicate that sodium fluoroacetate is rapidly degradable and it is expected at least 70% of the substance can be degraded biotically in the aquatic environment within 28 days.

5.1.6. Potential for or actual bioaccumulation in water

No published bioconcentration factor values (BCF), or octanol-water coefficient (K_{ow}) values were found for sodium fluoroacetate. On a weight-of-evidence assessment, sodium fluoroacetate is not considered to have potential for bioaccumulation in natural water because of its high water solubility and degradation by biotic metabolism.

5.1.7. Determination of classification for mixtures containing 1080

Classifications in subclass 9.1 were based on the known acute aquatic effects of technical 1080 (above) as the only known component of the formulation mixtures. These were considered mixture with a highly ecotoxic component (using the algal EC_{50} range 0f 0.012-.12 mg/L for active 1080), and a multiplier factor of 10 for the 1080 concentration was used to determine the weighed sum of the component, where less than 25% would mean a 9.1B classification or lower. The classifications for the formulations are set out in Table 2.

5.2 **Subclass 9.2 Soil Ecotoxicity**

Classification of 1080 active:	**9.2B**

5.2.1. Summary of data supporting classification

Soil invertebrate data for 1080 includes a 14-day LC_{50} for earthworms of 296 mg/kg with 95% confidence intervals of 228 - 402 mg/kg (O'Halloran & Jones 2003). An earthworm EC_{50} value was derived by dividing the lowest toxicity value by a safety factor of 10 (= 23 mg/kg). The NOEC, LOEC and EC_{50} for *Eisenia fetida* exposed to 1080 in a chronic test were 50, 100 and 160 mg/kg, respectively, for juvenile production, and 50, 100 and 90 mg/kg, respectively, for cocoon production (O'Halloran et al. 2005). LC_{50} and EC_{50} values for 1080 in soil to common garden snails exceeded 1500 mg/kg (O'Halloran & Jones 2003).

A 14-day germination and plant growth test conducted according to acceptable test methodology OECD 218 (O'Halloran et al. 2005). The lowest-observed-effect concentration (LOEC) of 1080 on lettuce seedlings was 7 mg/kg dry weight soil, at which the time to

emergence significantly increased. A significant decrease in seedling shoot growth also occurred. A median effective concentration (EC_{50}) value of 10 mg 1080/kg dry weight soil was derived for lettuce shoot growth. Lettuce seedlings appeared to be relatively more sensitive to 1080 soil concentrations than oat seedlings, for which LOEC and EC_{50} values were 22 and 42 mg/kg dry soil weight, respectively.

Sodium fluoroacetate is considered biodegradable in soils and the following DT_{50} values have been reported: 10 days at 27ºC, 30 days at 10ºC and 80 days at 5ºC, indicating temperature dependence of degradation rate in soil. Sodium fluoroacetate is not considered to have potential for bioaccumulation in natural soil because of its high water solubility and degradation by biotic metabolism. However, no observations regarding the effects of 1080 on soil invertebrates are available from field trials or efficacy tests.

5.2.2. Toxicity to soil invertebrates and plants

Soil invertebrate toxicity of 1080 has been determined using New Zealand-naturalised species of earthworm *Aporrectodea calignosa* and the common garden snail *Helix aspersa* (O'Halloran & Jones 2003). In this study, a 14-day LC_{50} for earthworms was 296 mg/kg with 95% confidence intervals of 228 - 402 mg/kg.

An additional assessment of the toxicity of 1080 to earthworm (*Eisenia fetida*) growth and reproduction determined a NOEC, LOEC and EC_{50} of 50, 100 and 160 mg/kg, respectively, for juvenile production, and 50, 100 and 90 mg/kg, respectively, for cocoon production.

While the minimum degrees of hazard regulations assess ecotoxicity to soil invertebrate in terms of an EC_{50} value, the OECD 207 protocol determines an LC_{50} value. The ERMA guidance recommends that the LC_{50} value can be conservatively converted to an EC_{50} value by dividing by 10, therefore the derived 14-day EC_{50} for earthworms is 23 mg/kg. It was noted that although the OECD 207 is not a chronic test and therefore does not derive LOEC values, a statistically significant inhibition of earthworm growth were observed at concentrations of 50 mg/kg and above, suggesting that the derived EC_{50} value of 23 mg/kg approximates a threshold for adverse effects in earthworms. Conversely, snails exposed to 500, 1000 and 1500 mg 1080/kg soil for 14 days following a similar test protocol experienced no mortality. Therefore, the snail 14-day LC_{50} exceeded 1500 mg/kg . The test was extended to 28 days, after which no mortality or effects on growth were observed at any of the test concentrations. Snails appeared to be able to absorb and retain significant levels of 1080 (tissue residues of up to 60 mg 1080/kg bw were measured at 28 days) without causing mortality (O'Halloran and Jones 2003).

Plants can absorb 1080 through their roots and in some instances toxic effects on plants have been recorded at relatively high concentrations of fluoroacetate (e.g Polter 1967; Cooke 1976; Hilton et al 1969; Ward and Huskisson 1972). Broad bean plants were shown to take up fluoroacetate through the roots and subsequently become toxic to aphids feeding on them. Concentrations in the plants necessary to kill the aphids were approximated at 1 mg 1080 per kilogram of plant tissue, when applied to the plant through a cut tap-root (David 1953). Defluorination (i.e. detoxification) of 1080 has been demonstrated in plants (Preuss and Weinstein 1969; Ward and Huskisson 1972; Vickery and Vickery 1975).

In a recent New Zealand field study, single 0.15% 1080 cereal pellet baits were placed at the base of individual plants of two species, pikopiko (*Asplenium bulbiferum*) and karamuramu (*Coprosma robusta*). Plants were sampled at various times up to 56 days, and samples analysed for 1080 content. No 1080 was detected in any of the pikopiko samples, whereas 1080 was detected in karamuramu, at a maximum concentration of 5 ppb after 7 days, and 2.5

ppb after 14 days. This concentration decreased to zero at 28 days, indicating that while karamuramu was shown to take up 1080, it was not persistent (Ogilvie et al. 2006).

Percentage germination, time to emergence, and root and shoot growth were monitored in a monocotyledon (oat, *Avena sativa*) and a dicotyledon (lettuce, *Lactuca sativa*), following OECD test guideline 208 (O'Halloran et al. 2005). Five replicates with six seeds per replicate of both plant species were exposed to 0, 0.32, 1.0, 3.2, 10.0, 32.0, and 100 mg 1080 / kg soil (dry weight) under controlled laboratory conditions. The seeds were checked daily and their time to emergence recorded. After 14 days, seedlings were harvested and the root and shoot weights measured. Lettuce was clearly more sensitive than oats with a median effective concentration (EC_{50}) for inhibition of germination at 47 mg 1080 / kg soil. Time to emergence for lettuce seedlings increased with increasing 1080 concentration, with a lowest observable effect concentration (LOEC) of 10 mg 1080 / kg soil. Growth of lettuce seedlings was also significantly inhibited at this concentration. Based on the EC_{50} results, active/technical 1080 would be classified into 'Category 9.2B: Substances that are ecotoxic in the soil environment'.

5.2.3. Toxicity to soil micro-organisms

It is known that fluoroacetate can have inhibitory effects on the metabolism of some micro-organisms found in soil and sediments. A study has been recently conducted (O'Halloran et al. 2005) to determine the EC_{25} value for 1080 on soil microbial function according to acceptable test methodology (OECD guideline 216). No 1080-related inhibition of soil nitrate production was found. The addition of possum urine to soils enhanced basal nitrate production, probably by supplying soil microbes with an easily convertible source of nitrogen (N) as nitrate. The urine from possums that had received a lethal dose of 1080 caused a 15% reduction in substrate-induced nitrate production compared with that in soils spiked with control urine. However, in terms of ecotoxicological hazard, this reduction was considered neither statistically nor biologically significant. No consistent concentration-related changes in nitrate production occurred in soils amended with 1080, and no significant inhibition of microbial nitrification occurred, compared with the untreated controls. The active 1080 does not trigger the minimum degrees of hazard threshold for being ecotoxic to soil microbial nitrogen mineralisation.

5.2.4. Degradation in soil

No published half-life values for 1080 in soil were found. Laboratory studies have shown that 1080 is defluorinated both by organisms which have been isolated from soil (Walker and Bong 1981; Wong et al. 1992, 1992a) and within soils themselves (David and Gardiner 1966; Parfitt et al. 1994). If 1080 is not removed from soil by water movement (leaching) most NZ soils can be expected to contain micro-organisms with enzymes capable of degrading 1080 (Walker 1994). Studies show that 1080 can be metabolised by soil micro-organisms, such as *Pseudomonas* and *Fusarium* species (Walker and Bong 1981; King et al. 1994). The enzymes capable of defluorinating (breaking down) 1080 have been isolated from some micro-organisms. The fluoride carbon bond is cleaved and ultimately enzyme-bound intermediates form non-toxic metabolites such as glycolate (O'Hagan and Harper 1999). In mild weather or warm conditions, such as 11–20ºC and 8–15% moisture, 1080 may be significantly defluorinated in 1–2 weeks. In less favourable conditions breakdown might take several weeks and, in extreme cold and drought, 1080 residues might persist in baits or in the soil for several months (King et al 1994).

In soils 1080 biodegradation was observed to take longer than in streamwater, and rate of biodegradation increased with temperature and moisture content (Parfitt et al 1994). Parfitt and colleagues (1994) calculated the DT_{50} in Kaitoke soils to be 10 days at 27ºC, 30 days at 10ºC and 80 days at 5ºC. In field trials carried out in New Zealand, samples of soil were taken after

three aerial applications in 1997-98 using 0.15% 1080 cereal (pellet type unspecified) bait. These samples were taken three random points in each of ten randomly selected fixed sites of 20 m^2 within the baiting areas, and from three random points in each of five randomly selected fixed sites of 20 m^2 outside the baiting areas. There were detectable, but low (mean 0.0092 ppm) 1080 residues of 1080 in soil after two of three of the operations. The mean concentrations of 1080 in soil outside the two baiting areas appeared to be lower than those inside (Wright et al 2002). Samples of leaf litter were also taken in this study, using the same plots and sampling regime. There were detectable, but low amounts of 1080 at Days 1, 5 and 30 post-baiting. The highest concentration found in a leaf litter sample was 0.19 ppm on Day 5 from inside one treatment area; all remaining leaf litter samples with detectable 1080 were below 0.01 ppm and were from up to 600 m outside one of the treatment areas. It was suggested that these 'outside' results were due to baits or fragments reaching the ground close to the sampling plots (Wright et al 2002).

In 1996–97, the Southland Regional Council monitored the fate of 1080 when 12000 kg of 1080 bait were disposed of in a landfill. Bore water samples taken adjacent to the disposal pit contained 1080 concentrations either below or close to Minstry of Health guidelines. No 1080 was detected after 10 months (Bowman 1999). On a weight-of-evidence assessment, sodium fluoroacetate is considered biodegradable in soils and not considered to have potential for bioaccumulation in natural soil because of its high water solubility and degradation by biotic metabolism.

5.2.5. Determination of classification for mixtures containing 1080

The condition for hazard cut-off levels in the Soil Ecotoxicity Subclass are "The substance is present at less than 1% and DT_{50} in soil is <30 days unless the substance soil ecotoxicity value is less than 0.1 mg/kg (that is highly ecotoxic)".

Active ingredient 1080 is not classified here as highly ecotoxic, however the DT_{50} in soil can be less than 30 days at warmer temperatures (27°C), but greater than 30 days at cooler temperatures (5°C). Applying a DT_{50} value >30 days, in the absence of data regarding the soil ecotoxicity of 1080 formulations, the classification 9.2C best describes formulations containing greater than 1% 1080, with no classification assigned to formulations containing less than 1% 1080.

Note that ERMA New Zealand have not classified 1080 or its formulations as 9.2. ERMA New Zealand will evaluate the new information and review the classifications as appropriate during the reassessment.

5.3 **Subclass 9.3 Terrestrial Vertebrate Ecotoxicology**

Classification of 1080 active:	**9.3A**

5.3.1. Summary of data supporting classification

Acute avian and mammalian oral LD_{50} values for 1080 are ≤50 mg/kg, and acute avian LC_{50} values are ≤500 parts per million in diet, indicating a classification of 9.3A – a substance very ecotoxic to terrestrial vertebrates.

5.3.2. Oral toxicity

Sodium fluoroacetate is a broad-spectrum toxin although there are some differences in susceptibility via oral intake between, and even within, species. The extremely toxic nature of

1080 when ingested or injected is well recognised and there is an extensive database on the acute oral toxicity of 1080 in birds, mammals and reptiles (Atzert 1971; Rammell & Fleming 1978; Eisler 1995). Table 1 summarises the acute oral toxicity (LD_{50} values) of 1080 to native and introduced species of mammals (King 1990) and birds (Heather and Robertson 1996) known to be present in New Zealand. At least one study of avian acute dietary toxicity meets an acceptable test methodology (Konenen et al. 1991); in standard 8-day toxicity tests with mallards (*Anas platyrhynchos*) and northern bobwhite quail (*Colinus virginianus*) exposed to a range of 1080 dietary concentrations, LC50 values were 527 and 385 ppm respectively. Additional tests in this study indicated that mallards and northern bobwhite avoided consumption of 1080-treated food at concentrations equal to or greater than 236 and 95 ppm respectively (Kononen et al 1991).

Mallards avoided consumption of 1080-treated water at 13-24 ppm and northern bobwhites at concentrations greater than 9 ppm. While many of the data in Table 13 were probably not strictly derived from acceptable test methodologies, the consistently high toxicity of 1080 demonstrated in a wide range of mammals and birds provides strong weight of evidence for the classification above.

Table 3 | **Acute oral toxicity of 1080 to terrestrial species (native New Zealand species shaded)**

Mammals **Species**	**LD_{50} (mg/kg)**	**Reference**
Bennett's wallaby (*Macropus rufogriseus*)	0.21	Munday (1978)
Dama/ Tammar wallaby *(M. eugenii)*	0.27	Munday (1978)
Brushtail possum (*Trichosurus vulpecula*)	0.79	Bell (1972)
Dog (*Canis familiaris*)	0.06	Chenoweth (1949)
Cat (*Felis domesticus*)	0.35	Eason and Frampton (1991)
Ferret (*Mustela putorius*)	1.41	Tucker and Crabtree (1970)
Rabbit (*Oryctolagus cuniculus*)	0.35	McIlroy (1982)
House mouse (*Mus musculus*)	8.3	McIlroy (1982b)
Rat (wild) (*Rattus norvegicus*)	0.22-3.0	Chenoweth (1949)
Cattle (*Bos taurus*)	0.39	Robison (1970)
Deer (not specified)	0.50	Rammell and Fleming (1978)
Horse (*Equus caballus*)	0.32-1.0	Atzert (1971)
Pig (*Sus scrofa*)	0.40	Atzert (1971)
Sheep (*Ovis aries*)	0.25-0.64	Atzert (1971)
Goat (*Capra hircus*)	0.3-0.7	Atzert (1971)
Short-tailed bat (*Mystacine tuberculata*)	0.15 (estimate)	Lloyd and McQueen (2000)

Birds **Species**	**LD_{50} (mg/kg)**	**Reference**
Mallard duck (*Anas platyrynchos*)	4.8	Hudson et al. (1972)
Pacific black duck (*Anas superciliosa*)	10.0	McIlroy (1984)
Common pigeon (*Colombia livia*)	4.250	Tucker and Crabtree (1970)
Chicken (*Gallus gallus*)	7.0 –8.0	Cottral et al. (1947)

Birds		
Species	**LD_{50} (mg/kg)**	**Reference**
Chukar partridge (*Alectoris chukar*)	3.51	Tucker and Crabtree (1970)
Ring-necked pheasant (*Phasianus colchinus*)	6.46	Tucker and Crabtree (1970)
California quail (*Callipepla californica*)	4.60	Tucker and Crabtree (1970)
European goldfinch (*Carduelis carduelis)*	3.5 approx	McIlroy (1984)
Australian magpie (*Gymnorhina tibicen)*	9.9	McIlroy (1984)
Weka (*Gallirallus australis greyi*)	8.0	McIntosh et al. (1966)
Silvereye (*Zosterops lateralis*)	9.25 approx	McIlroy (1984)

No toxicity data relating to New Zealand amphibian or reptile species are available. However, acute LD_{50} values for other amphibians range from 54.4 mg/kg for bullfrog (*Rana catesbeiana*) (Tucker and Crabtree 1970), 60 mg/kg for Spotted grass frog (*Limnodynastes tasmaniensis)* (McIlroy et al. 1985), 150 mg/kg for Leopard frog (*Rana pipiens*) (Atzert 1971) and >500 mg/kg for South African clawed toad (*Xenopus laevis*) (Atzert 1971). Acute LD_{50} estimates for other reptiles from areas without fluoroacetate-bearing vegetation range from 43.6 mg/kg for Gould's monitor (*Varanus gouldi)*, <110 mg/kg for bearded dragon (*Pogona barbatus*), <119 mg/kg for Lace Monitor (*Varanus varius*), 206 mg/kg for Shingle-back lizard (*Tiliqua rugosa*) and 336 mg/kg for blotched blue-tongue lizard (*Tiliqua nigrolutea*) (McIlroy et al. 1985). This suggests that frogs and reptiles respectively are relatively less susceptible to 1080 than mammals and birds.

5.3.3. Determination of classification for mixtures containing 1080

The classifications shown for formulation groupings are based on ratio of an LD_{50} value of 0.06 mg/kg (highest reported terrestrial toxicity) according to % w/w of active 1080 present in the formulations. These classifications were considered appropriate given that nearly all of the formulations are baits designed for terrestrial vertebrate pest control, and there is evidence that accidental poisoning of domestic and wildlife species by bait formulations can occur in some instances.

5.4 Subclass 9.4 Terrestrial Invertebrate Ecotoxicity

5.4.1. Summary of data supporting classification

Based on a bee study which gave a 24-hr oral LD_{50} of 0.8 μg/bee, and an ant study which gave a 24-hr oral toxicity value of 0.14 μg/ant, and a 48-hr LD_{50} of 0.08 μg/ant, 1080 is classified as 9.4A – 'very ecotoxic to terrestrial invertebrates'. The bee test, however, was conducted prior to the publication of any standardised guidelines, and there are no specified guidelines for determining toxicity to ants.

5.4.2. Acute toxicity to terrestrial invertebrates

1080 is recognised as highly toxic to some insect species, and has been used experimentally as an insecticide for fleas, aphids and wasps (David, 1950; Spurr, 1991). 1080 was patented as an insecticide in Germany (Tieutze et al. 1930, cited in Twigg, 1990). Lethal doses, summarised in Table 2, range from 1 mg/kg up to 200mg/kg. Exposure methodology and measured endpoint vary greatly between studies, thus making comparisons of species sensitivity to 1080 difficult. In general, toxicity is expressed in terms of dose per kg body weight, so that toxicity of substances can be compared across different species. The table below illustrates that adverse effects are generally observed in invertebrates at doses of 1080 less than 100 mg/kg. Apart from a

nematode study where exposure was via direct contact with 1080 in solution (Middendorf and Dusenbery 1993), laboratory studies with terrestrial invertebrates have focused on oral toxicity.

Table 4 | Acute oral toxicity (LD_{50} values) of 1080 to terrestrial invertebrates (Shaded species present in New Zealand)

Species	Toxic dose*	Exposure methodology	Reference
Honey bee (*Apis mellifera*)	8 mg/kg = 0.8 μg/bee	24 hr oral LD_{50}	Palmer-Jones 1958
Striated ant (*Huberia striata*)	72 mg/kg = 0.14 μg/ant 42 mg/kg – 0.08 μg/ant	24 hr oral LD_{50} 48 hr oral LD_{50}	Booth & Wickstrom 1999
Steel-blue sawfly (*Perga dorsalis*)	1.05 mg/kg	5 day LD_{50} via abdominal injection	Twigg 1990
House fly (species unspecified)	21 mg/kg	LD_{50} via thoracic injection	Matsumura & O'Brien 1963
Common wasp (*Vespula vulgaris*)	<10 mg 1080 /kg bait	Lethal to individual wasps	Spurr 1991
Unspecified wasp (*Bracon hebetor*)	0.025 mg/kg	Reduced oocyte production following injection	Smith & Grosch, 1976
Nematode (*Aenorhabditis elegans*)	76 mM 23 mM	24 hr LC_{50} Reproductive EC_{50}	Middendorf & Dusenbery 1993.
American cockroach (species unspecified)	43 mg/kg	LD_{50} - abdominal injection	Matsumura & O'Brien 1963
Native cockroaches (*Celatoblata Undulivitta, C. vulgaris & C. subcorticaria*)	Dose not calculated	Mortality & behavioural effects in cockroaches fed 0.08% 1080 baits.	McIntyre 1987
Butterflies & moths *Mnesamplea privata* *Ochrogaster lunifer* *Spilosoma* spp.	 3.9 mg/kg 200 mg/kg 42.7 mg/kg	 5 day LD_{50} via abdominal injection	 Twigg 1990
Native Tree weta (*H. crassidens*)	91 mg/kg ~ 60 ug/weta 15 mg/kg ~ 60 μg/weta	LD_{50} not toxic dose	Cited in Booth & Wickstrom 1999 Eason et al. 1993

*Unless otherwise expressed dose is given in mg 1080 per kg body weight

Worker bees were exposed to various amounts of 1080 dissolved in sucrose solution and mortality assessed after 24 hrs (Palmer Jones, 1957). The methods are described in the paper and appear to follow a similar protocol to those recommended by the ERMA guidance for determining oral toxicity to terrestrial invertebrates, however it is unclear whether or how many replicates were used, how many test concentrations there were or how the LD_{50} was derived. A low percent mortality (7-12%) was reported for ants (*Huberia striata)* offered 1080 cereal baits (0.15%) under controlled laboratory conditions (Booth and Wickstrom, 1999). The paper reports 24-hr and 48 hr LD_{50} values for ants in terms of body weight. However the HSNO 'minimum degrees of hazard' threshold for terrestrial invertebrates is given in terms of amount of substance per invertebrate. The average weight of an ant is 2 mg (Booth and Wickstrom, 1999) which allows calculation of the 24-hr and 48 hr LD50 at 0.14 μg/ant and 0.08 μg/ant, respectively.

No mortality was observed in tree weta dosed with 15 mg/kg 1080 (Eason et al. 1993). The LD_{50} for this species is around 91 mg/kg (unpublished data). Assuming a tree weta weighs around 4 g (Booth et al, 2001) this is equivalent to an approximate no effect level of 60 μg/weta, and an LD_{50} of 365 μg/weta. No other data was available that would allow conversion into the required units to compare to the HSNO minimum degrees of hazard threshold (of μg substance/individual invertebrate). Obviously the smaller the invertebrate the more 'toxic' the substance will appear according to this threshold.

There are other some reports of 1080 toxicity observed in native cockroaches, however no LD_{50} values are given. Native cockroaches were fed 1080 (0.08%) on control baits in the form of pelletised poultry mash, and mortality was observed at daily intervals over two weeks (McIntyre, 1987). Although the LD_{50} for 1080 was not calculated survivorship curves over the 14 day period indicate the susceptibility of the three species of cockroaches tested (*Celatoblatta undulivitta, C. vulgaris and C. subcorticaria*). During the exposure period, the cockroaches fed 1080 baits had reduced responsiveness to stimuli and show abnormal escape and orientation responses. Conversely, earlier studies by Matsumura and O'Brien (1963) reported hyperexcitability and convulsions in American cockroaches that had received sublethal doses of 1080 via abdominal injection.

5.4.3. Field-based evidence of 1080 toxicity in terrestrial invertebrates

Insects, including slugs and ants, have been observed feeding on baits and on poisoned animals (Lloyd and McQueen, 2000; Notman, 1989; Spurr and Drew, 1999), and are therefore at risk to 1080 poison. In addition, there are reports of incidental invertebrate mortalities associated with 1080 applications (e.g. Hegdal et al., 1986; McIntyre, 1987). McIntyre (1987) reported low numbers of native cockroaches (trapped live, method unspecified) following the aerial application of 1080 baits in the form of pelletised poultry mash (0.08% 1080) in New Zealand. Unfortunately this study did not monitor a matched control plot to confirm that the low numbers were due to 1080 poisoning. However, observation of the trapped cockroaches indicated that cockroaches were eating the baits and a high mortality in those cockroaches was observed. In the surviving cockroaches, 'abnormal' behaviour was reported: cockroaches were slow and lethargic; easily captured; moribund or slow to recover from the carbon dioxide treatment used to facilitate handling.

In a controlled field study using cereal baits (0.15% 1080 hand spread over a grid at the equivalent rate of 5.8 kg bait/ha), the number of invertebrates reported feeding on baits was lower when the baits contained 1080, suggesting a toxic effect of 1080 on those populations (Sherley et al. 1999). However the effect appeared to be transient and numbers recovered within 6 days of toxic bait removal. The authors concluded that at any one time, only a small proportion of baits have invertebrates on them, and the few individuals per bait represent a small section of the fauna present in forest litter (Sherley et al. 1999). This conclusion was corroborated by the results of a study by Spurr and Drew (1999).

Other (New Zealand) studies report limited impacts on invertebrate populations following 1080 applications. No mortality was reported in cockroaches, centipedes, millipedes, kauri snails, and all but 1 beetle that were trapped in enclosures with 1080 baits (unpublished report by Pierce and Montgomery 1992, cited by Spurr 1994b). Spurr (1994a) reported no significant impacts on invertebrate populations monitored by pitfall traps following 1080 aerial applications (0.08% 1080, sown at 5kg bait/ha) in a matched controlled study. No reductions in tree weta were measured and no dead insects were found around baits following 1080 operations (Unpublished report by Anon 1990, cited in Spurr 1994b, Spurr et al, 2002). Aspin et al. (1999) also observed

no impacts on the numbers of ground dwelling insects up to 1 year following an aerial 1080 application. Overall, the literature suggests that invertebrates will eat and come into contact with 1080 baits following aerial application, and that individual toxicity is likely, however long term adverse impacts at the population level have not been observed and are considered unlikely.

5.4.4. Determination of classification for mixtures containing 1080

A simple ratio of the lowest LD_{50} value in terrestrial invertebrates (48-hr LD_{50} of 0.08 μg/ant) to the % w/w of active 1080 in formulations indicates the classifications shown in Table 2. The wasp bait formulation was classified as 9.4B as it is a formulation intended to be applied for control of a pest invertebrate species.

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