HEALTH RISK ASSESSMENT: DRAIN CLEANER

Prepared as part of a Ministry of Health contract for scientific services

by

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February 2015

Client Report FW14016

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GLOSSARY

Acuity	Sharpness of perception
Acute toxicity	 Adverse effects of finite duration occurring within a short time (up to 14 d) after administration of a single dose (or exposure to a given concentration) of a test substance or after multiple doses (exposures), usually within 24 h of a starting point (which may be exposure to the toxicant, or loss of reserve capacity, or developmental change, etc.)
	2. Ability of a substance to cause <i>adverse effects</i> within a short time of dosing or <i>exposure</i>
Adherent leucoma	A white tumor of the cornea enclosing a prolapsed adherent iris
Adverse effect	A change in biochemistry, physiology, growth, development morphology, behaviour, or lifespan of an organism which results in impairment of functional capacity or impairment of capacity to compensate for additional stress or increase in susceptibility to other environmental influences
Alkaline	The property of having a pH of greater than seven (pH7)
Alkalis	Inorganic compounds, which are water soluble hydroxides of the group 1 metals; or ammonium hydroxide.
Alveolar	Pertaining to the air sacs of the lung where gases are exchanged during the process of respiration
Anterior staphyloma	Protrusion of the sclera or cornea, usually lined with uveal tissue, due to inflammation in the anterior part of the eye
Antral stenosis	Narrowing of the passage between the stomach and the small intestine
Caustic	Burning or corrosive; destructive to living tissues
Cilia	A hair-like appendage which is found in numbers on the surface of a cell
Cicatrical ectropian	An eversion of the eyelid due to scar tissue
Conjunctivitis	Inflammation of the conjunctiva, the membrane which covers the front of the eye
Corrosive	Producing gradual destruction of tissues by the action of a strong acid or alkali
Dermal	Cutaneous, pertaining to the skin
Dose	Total amount of a substance administered to, taken up, or absorbed by an organism, organ, or tissue
Dose response	Association between dose and the incidence of a defined biological effect in an exposed population

Dose response assessment	Analysis of the relationship between the total amount of an agent administered to, taken up by, or absorbed by an organism, system, or (sub)population and the changes developed in that organism, system, or (sub)population in reaction to that agent, and inferences derived from such an analysis with respect to the entire population. Dose– response assessment is the second of four steps in risk assessment
Epithelium	Sheet of one or more layers of cells covering the internal and external surfaces of the body and hollow organs
Erythema	Redness of the skin due to congestion of the capillaries
Exposure assessment	Evaluation of the exposure of an organism, system, or (sub)population to an agent (and its derivatives). Exposure assessment is the third step in the process of risk assessment.
Harm	An adverse effect. Damage or adverse effect to a population, species, individual organism, organ, tissue, or cell
Hazard identification	The identification of the type and nature of adverse effects that an agent has an inherent capacity to cause in an organism, system, or (sub)population. Hazard identification is the first stage in hazard assessment and the first of four steps in risk assessment.
Hydroxide solution(s)	An aqueous solution containing the hydroxide (OH ⁻) ion as the ion of interest. The solution does not contain hypochlorite ion derived from added sodium hypochlorite
Incidence	Number of occurrences of illness commencing, injury, or of persons falling ill, during a given period in a specific population usually expressed as a rate
Injury	Any physical harm or damage serious enough to warrant medical treatment by a health professional either at the scene or in a hospital or primary care practice.
Irritant	Producing inflammation or irritation
Ischemic necrosis	Cell or tissue death due to reduced blood supply
Liquefaction necrosis	Tissue death from liquefying effect of a substance
Lymphadenoid tissue	Tissue resembling that of lymph nodes, found in the spleen, bone marrow, tonsils, and other organs
NaOH	Sodium hydroxide, caustic soda, lye
Necrosis	Morphological changes indicative of cell death
No observed adverse effects level (NOAEL)	Greatest concentration or amount of a substance, found by experiment or observation, that causes no alterations of morphology, functional capacity, growth, development, or life span of target organisms distinguishable from those

	observed in normal (control) organisms of the same species and strain under the same defined conditions of exposure
Ocular	Pertaining to the eye
Oesophageal	Of or relating to the oesophagus
Oesophageal stricture	A narrowing of the oesophageal lumen which may result from prior exposure to caustic agents
Oral	Pertaining to or via the mouth
Permanent harm	An adverse effect from which the subject does not recover
Pharynx	The throat; the musculomembranous cavity behind the nasal cavities, mouth, and larynx, communicating with them and with the oesophagus
Phthisis bulbi	Shrinkage of the eyeball
Pseudopterygium	Adhesion of the conjunctiva to the cornea
Pyogenic granuloma	A benign, solitary nodule resembling granulation tissue, found anywhere but often in the mouth, usually at the site of trauma as a tissue response to nonspecific infection
Rhinitis	Inflammation of the mucous lining of the nose
Risk characterisation	The qualitative and, wherever possible, quantitative determination, including attendant uncertainties, of the probability of occurrence of known and potential adverse effects of an agent in a given organism, system, or (sub)population, under defined exposure conditions. Risk characterization is the fourth step in the risk assessment process.
Sclera	The tough white outer coat of the eyeball, covering approximately the posterior five-sixths of its surface, continuous anteriorly with the cornea and posteriorly with the external sheath of the optic nerve
Stricture	Abnormal narrowing of a duct or passage such as blood vessels or urethra
Toxicological endpoints	An observable or measurable biological event or chemical concentration (e.g., metabolite concentration in a target tissue) used as an index of an effect of a chemical exposure
Trichiasis	Ingrowing eyelashes

SUMMARY

Hazards associated with exposure to drain cleaner products will be largely due to the high concentration of corrosive sodium hydroxide (NaOH) in these products. Products currently sold in New Zealand fall into two broad categories; crystals containing approximately 55-60% NaOH and liquids or gels containing 3-19% NaOH.

NaOH occurs naturally in the body and there is no evidence that it is systemically toxic. NaOH is potentially corrosive to all tissue types. The extent and degree of harm will be a function of the concentration of the hydroxide ion, the area affected and the contact time before removal or dilution. At low concentrations (0.5-2.0%) NaOH is an irritant. As the concentration increases chemical burns occur, with the severity and depth of the burns increasing with NaOH concentration and contact time. The concentration of NaOH in drain cleaner products is well above guidance concentrations at which severe chemical burns would be expected (5.0%). While there may be some limited capacity for human body fluids to dilute NaOH to non-corrosive concentrations, this should not be assumed. It should be considered that exposure of the skin, eyes or gastrointestinal tract to NaOH of sufficient concentration (>2.0%) has the potential to cause harm, irrespective of the volume of exposure.

Potential exposure scenarios were considered, including accidental ingestion by children and accidental dermal or ocular exposure by children and adults. Qualitative assessment of possible exposure scenarios suggests that the circumstance with the greatest probability of serious harm is ingestion of liquid drain cleaner by young children (less than five years of age). Due to the sensitivity of the tissues involved and the difficulty of rapidly decontaminating the gastrointestinal tract, it must be assumed that harm may occur following ingestion of even the smallest volume of drain cleaner. While there is potential for serious ocular damage if any but the smallest volume of drain cleaner contact the eye, there are no reports of this happening in New Zealand. Child-resistant measures on containers of these products will mitigate the risk of injury and introduction of such measures in Denmark was related to a temporal decline in the incidence of caustic ingestion incidents in Denmark.

Surveillance of chemical injuries in New Zealand has not identified drain cleaner as a noticeable contributor. While there is potential for under-reporting (occurrence of injuries or incidents that do not come to the attention of the surveillance systems), unreported cases of drain cleaner injury will probably not be in the more severe categories.

1. INTRODUCTION

The purpose of this report is to develop a generic health risk assessment for household drain cleaner. This report will only consider domestic, non-occupational, routine and incidental exposure to household drain cleaner. In some instances, occupational exposure information will be used to contextualise non-occupational exposures, specifically in terms of adverse health outcomes and critical exposure levels. Exposure scenarios will be developed for the most common or likely exposure events to assess the health risk for vulnerable groups. The report will be a qualitative assessment of the health risk posed by exposure to household drain cleaner.

1.1 Consumer Products Description – Drain Cleaner

Drain cleaners are chemical preparations in the form of a solid, liquid or gel that are applied to the effluent outlet of sinks, toilets, tubs or shower to remove soft obstructing material such as grease or hair. Drain cleaning products are usually composed of a strong alkali (e.g. sodium or potassium hydroxide) or a strong acid (e.g. sulphuric). Less commonly, drain cleaners may be solvent-based or may contain lytic enzymes, such as lipases and proteases.

Drain cleaners available for purchase by the general New Zealand public are almost exclusively of the strong alkali type. Some enzyme-based products are available, but details from material safety data sheets (MSDS) suggest that the enzymes used in these preparations are not a human health risk. Other ingredients are added to drain cleaners to provide various technological functions. Table 1 lists some of the major products available in New Zealand and their ingredients, as stated in MSDSs. It should be noted that the market for drain cleaners appears to be quite fluid, with minor manufacturers entering and leaving the market at regular intervals.

Brand name	Manufacturer	Ingredients	Proportion (%)	Function
Drano® crystals clog remover ¹	SC Johnson	Sodium hydroxide Aluminium chips ³ Sodium nitrate Sodium chloride Sun Chemical Pigment Green 7	30-60 (Label 54.2) 1-5 30-60	Caustic Stabiliser Stabiliser Carrier Dye
Drano® Max gel ¹	SC Johnson	Water Sodium hypochlorite Sodium hydroxide Proprietary surfactant blend Sodium silicate	5.0-10.0 1.0-5.0 1.0-5.0	Bleach Caustic Cleaning agent Corrosion inhibitor
Drain Clean® Crystals ²	Pascoes Pty Ltd	Sodium hydroxide Alkaline salts Aluminium ³	30-45 (Label 55) >50 ≥5	Caustic
Drain Clean® Liquid²	Pascoes Pty Ltd	Sodium hydroxide Non-ionic surfactants	10-20 (Label 16 or 19) <5	Caustic

Table 1:Ingredient composition of drain cleaners commonly used in New
Zealand

Brand name	Manufacturer	Ingredients	Proportion (%)	Function		
		Water	To 100			
Drain Clean® ultra gel ²	Pascoes Pty Ltd	Sodium hydroxide Other non-hazardous ingredients	15-18 (Label 18.5) 1-2	Caustic		
-		Water	To 100			

¹ Information obtained from <u>http://www.whatsinsidescjohnson.com/en-us/products-by-brand/drano.aspx</u>

For most of these products the proportion of an ingredient was only available if the hazardous chemical was present at or above reportable levels as defined by OSHA 29 CFR 1910.1200 or the Canadian Controlled Products Regulations.

² Information obtained from <u>http://drainclean.com.au/</u>

³ Aluminium is added to crystal drain cleaners in the form of metal turnings. These react with sodium hydroxide when wetted to cause mechanical agitation

An informal survey of drain cleaner products available through New Zealand retail outlets was conducted during December 2014. The main types of drain cleaner products found were:

- Crystal products, containing 55-60% NaOH
- Liquid or gel products, containing 16-19% NaOH
- Gel products containing less than 5% NaOH and 4-10% sodium hypochlorite

While drain cleaner products may contain a range of ingredients, the only component present in all drain cleaners available in New Zealand, except enzyme-based products, is NaOH. A small number of products also contain appreciable concentrations of sodium hypochlorite (4-10%). While it is possible that, for these products, sodium hypochlorite may contribute to the overall risk, this is not generally true for drain cleaners. Further information on risks associated with sodium hypochlorite-based products have been considered in a separate hazardous substances assessment (Ashworth and Pattis 2014).

2 HAZARD IDENTIFICATION

- 2.1 Drain Cleaner
- 2.1.1 Previous assessments

No previous assessments of formulated drain cleaner were found.

2.1.2 Relevant toxicological studies

Scientific literature searches were carried out in Web of Science¹ and PubMed². Search terms included the 'drain' and 'cleaner' or 'opener' and any common variants and the wildcard term 'toxic*'.

No relevant toxicological studies were found.

2.1.3 Observations in humans

Incident surveillance and epidemiological studies

New Zealand

In New Zealand, data on hazardous substance exposure incidents is collated in the Hazardous Substances Surveillance System (HSSS) by the Massey University Centre for Public Health Research (CPHR). For the period 2006 to 2011, 5,827 incidents were reported to HSSS. Of these, 233 (4.0%) were listed using descriptors that included drain cleaner; alkali, caustic soda, drain cleaner, Drano, Mr Muscle, potassium hydroxide, sodium hydroxide and Tergo drain unblocker. However, only 14 incidents (0.24%) used descriptors that refer unequivocally to drain cleaner; drain cleaner, Drano and Tergo drain unblocker.

Information was provided by the New Zealand National Poisons Centre³ on the 20 substances accounting for most calls to the centre for each year during the period from 2008 to 2012. Drain cleaner was not in this 'top 20' list in any year for which information was available.

No fatalities due to ingestion of drain cleaner were reported in New Zealand in the period 2006 to 2009.

A 10-year review of eye trauma cases at Waikato Hospital found that 61 of 821 (7.4%) cases were due to chemical exposures (Pandita and Merriman 2012). The majority of chemical eye injuries (82%) occurred at work and involved NaOH or sodium hypochlorite. Chemical injuries in the home were usually due to cleaning agents. No information on the types of cleaning products causing chemical eye injuries in the home was presented.

¹ <u>http://isiknowledge.com/</u>

² <u>http://www.ncbi.nlm.nih.gov/pubmed</u>

³ <u>http://www.poisons.co.nz/index.php</u> Accessed 23 January 2014

United States

The American Association of Poison Control Centers (AAPCC) supports the United States network of 56 poison centres.¹ The association publishes an annual report including summary statistics of all exposures reported to the poison centres during a calendar year. Table 2 summarises the data for alkaline drain cleaners for the period 2002-2011.

Some distinct patterns of alkaline drain cleaner poisoning incidents are apparent from this table:

- Alkaline drain cleaners are involved in approximately 0.15% of all exposure events reported to US poison centres;
- The majority of those involved in alkaline drain cleaner exposure incidents are adult, but children less than six years of age make a disproportionate contribution to total incidents;
- The vast majority of reports of alkaline drain cleaner exposure relate to unintentional exposure, although intentional exposures account for approximately 5% of reported exposures. Of the more than two million exposures reported each year, intentional exposures account for approximately 15% of exposures, with suicidal intent suspected in approximately two-thirds of intentional exposures;
- Most alkaline drain cleaner exposures result in minor or no injury. However, 1–2% of exposures result in major injuries or death.

While the information presented in the US poisons centres reports is not always comprehensive, it appears that no more than 3 or 4 of the 41 fatalities reported in Table 2 were due to unintentional exposures, with the vast major of fatalities being the result of suicidal intent.

¹ <u>http://www.aapcc.org/</u> Accessed 25 November 2013

Year ¹	Exposures reported		Age	(yeaı	rs)			Reasor	1			Treated in healthcare facility	Outco	me ³			
	Total	Alkaline Drain Cleaner	<6	6- 12	13- 19	>19	Unknown	Unint	Int	Other	Adv Rxn		None	Minor	Mod	Major	Death
2002	2380038	3747	506	311		2869		3458	213	27	36	1152	452	1071	493	59	7
2003	2395582	4019	616	356		2981		3665	257	21	56	1244	498	1243	522	58	4
2004	2438644	3913	572	313		2971		3541	282	22	45	1231	513	1229	488	54	7
2005	2424180	3677	535	301		2779		3344	258	21	41	1201	501	1101	455	46	5
2006 ²	2403539	3583	490	212		1738		2644	165	23	23	813	388	760	297	37	2
2007	2482041	3792	553	242		1822		2873	164	21	30	895	412	818	337	34	4
2008	2491049	3861	561	245		1954		2972	170	30	30	972	502	827	360	30	3
2009	2479355	3422	479	97	102	1819	411	2659	178	27	28	833	410	714	300	36	2
2010	2384825	3221	425	71	94	1754	359	2452	171	23	45	815	332	693	281	47	6
2011	2334004	3331	437	88	96	1808	388	2582	164	24	29	823	406	748	321	40	1

Table 2: Incidents of alkaline drain cleaner poisoning reported to US poison centres 2002-2011

Unint = unintentional exposures, including passive environmental exposure, occupational exposure, therapeutic error or unintentional misuse Int = intentional exposures, including suspected suicide and improper or incorrect use of a substance for a purpose other than its intended purpose Adv Rxn = adverse reaction, an adverse event occurring with normal, prescribed, labelled, or recommended use of the product, as opposed to overdose, misuse, or abuse, including allergic, hypersensitive and idiosyncratic reactions

Mod = moderate

¹ Report references: (Bronstein et al 2007; Bronstein et al 2008; Bronstein et al 2009; 2010; Bronstein et al 2011; Bronstein et al 2012; Lai et al 2006; Watson et al 2003; Watson et al 2004; Watson et al 2005)

² From 2006 onwards there was a change in the way demographic information was reported; the 'Alkaline Drain Cleaner' exposure count represents all recorded exposures, but the counts in subsequent columns report single substance exposures only. Over all exposures, single substance exposures account for just over 90% of all exposures

³ Minor = The patient developed some signs or symptoms as a result of the exposure, but they were minimally bothersome and generally resolved rapidly with no residual disability or disfigurement. A minor effect is often limited to the skin or mucus membranes.

Moderate = The patient exhibited signs or symptoms as a result of the exposure that were more pronounced, more prolonged, or more systemic in nature than minor symptoms. Usually, some form of treatment is indicated. Symptoms were not life-threatening, and the patient had no residual disability or disfigurement

Major = The patient exhibited signs or symptoms as a result of the exposure that were life-threatening or resulted in significant residual disability or disfigurement

A retrospective case series (n = 633) of consecutive cases of chemical eye injury presenting at the emergency department at a large eye hospital in Alabama between 1 January 2006 and 31 December 2009 was reviewed (Blackburn et al 2012). The most common class of agents involved in chemical eye injuries were household cleaning agents (28.6% of cases), including 11 injuries (1.7% of total cases) due to drain cleaner. Chemical eye injuries due to household cleaning products involved cases with an average age of 32.8 years.

South Africa

Childhood poisoning incidents (n = 2,872) presenting to the Red Cross War Memorial Children's Hospital (RCWMCH) in Cape Town, South Africa, from 2003 to 2008 were reviewed (Balme et al 2012). Household cleaning products contributed the fourth largest number of incidents, after paraffin, drugs and pesticides. There were 299 single toxin household cleaning product incidents, with 28 incidents due to drain cleaner (1% of the total incidents). Poisonings due to household cleaning products were general of low severity, with no fatalities reported.

Spain (Galicia)

Case histories of children (n = 743) presenting at the Paediatric Department of the General Hospital of Galicia over the period January 1981 to December 1990 for suspected ingestion of caustic substances were reviewed (Casasnovas et al 1997). The mean age of cases was 27 months, with 85% of cases less than three years of age. Cases were approximately twice as likely to be male as female. Drain cleaner was the caustic substance ingested in 1.5% of cases, with bleach being the most commonly ingested substance (73%). While only 20% of all cases resulted in oesophageal burns, 55% of drain cleaner ingestion cases resulted in burns.

Canada

Case histories of children (n = 80) presenting at the Department of Otolaryngology, The Hospital for Sick Children, Toronto with caustic burns of the aerodigestive tract between 1965 and 1995 were reviewed (de Jong et al 2001). Ages ranged from one to 15, with 78% of cases between one and three years. The most common causative agent was drain cleaner (29 cases). The majority of burns (54%) were confined to the oral cavity, with only one case with documented gastric injury.

Turkey

Case histories of children (n = 75) managed in Yuzuncu Yil University, School of Medicine, Van, Turkey for corrosive substance ingestion were reviewed (Melek et al 2008). The mean age of cases was 3.5 years, with 82% of cases less than five years of age. Ingestion of drain cleaner accounted for 5.3% of cases (4 cases). The most commonly ingested corrosive substance was bleach (45% of cases). Ingested volumes of corrosive substance were in the range 1 to 100 ml.

A retrospective study of children (n = 320) referred to the Pediatric Emergency Department of Eskisehir Osmangazi University Hospital in 2009 for acute poisoning was conducted (Sahin et al 2011). Drugs were the most common cause of intoxication, followed by corrosive substances (23.1%). Corrosive ingestion cases were more likely to be under 4 years of age.

Cases admitted to the Department of Emergency Medicine, Dokuz Eylul University Hospital in Izmir due to caustic and household detergent exposure between 1993 and 2008 were reviewed (Arıcı et al 2012). Caustic exposures accounted for 8.5% of childhood cases and 4.1% of adult cases. Most of the cases were unintentional (96% of child cases, 76% of adult cases). Alkaline substances accounted for 58% of cases, although drain cleaner was not reported to be a major contributor.

Australia

A case series (n = 50) of paediatric caustic ingestion cases at Children's Hospital, Westmead was reviewed (Riffat and Cheng 2009). Although 74% of causative agents were alkali, the major contributors were dishwashing powder, disinfectants, oven cleaner and degreasers. Drain cleaner does not appear to have been a significant contributor to caustic ingestion cases in this case series.

United Kingdom

A prospective survey of accidental childhood poisonings (n = 2043) was carried out through nine accident and emergency departments and five paediatric departments, between July 1982 and February 1984 (Wiseman et al 1987). Most cases (75%) were two and three year olds, with 56% being males. While household products were responsible for 37% of cases, drain cleaner was not mentioned. The most commonly reported household products involved in childhood poisonings were bleach, detergents, disinfectants and petroleum distillate.

Between 1 March 2008 and 30 April 2009, the United Kingdom National Poisons Information Service (NPIS) prospectively collected 5939 telephone enquiries related to household cleaning products (Williams et al 2012). The majority of enquiries (65.5%) concerned children 5 years or less. Drain cleaner accounted for 69 enquiries (1.2%). However, drain cleaner incidents were over-represented amongst cases with moderate to serious outcomes, accounting for 5.3% of moderate outcomes and 22.2% of serious outcomes. It should be noted that the serious outcomes associated with drain cleaners (2 cases) related to intentional ingestion of acid drain cleaners by adults.

Chemical eye injuries presenting to the Croydon Eye Unit during a 14-month period (1 January 1985 to 28 February 1986) were analysed (Morgan 1987). Of 180 cases, 47 were due to exposure to alkalis. However, a breakdown of these injuries did not identify drain cleaner as a significant contributor.

Iran

A prospective case series of caustic substance ingestion cases admitted to the emergency ward of the Loqman-Hakim hospital, Tehran was examined (Yeganeh et al 2009). Of 1260 cases admitted between April 1999 and January 2006, 62 fatalities occurred (42 men, 20 women). Fatal cases were in the age range 15 to 107 years. Drain cleaner was responsible for 11 of the 62 fatalities (18%). The other main

causes of fatalities were; arsenic-based depilatory agents (n = 20), sulphuric acid (n = 12) and 'choloridric acid'¹ (n = 12).

Denmark

Case information for children less than 16 years (n = 102) admitted for caustic ingestion during the period 1976-1991 in the county of Aarhus, Denmark was reviewed (Christesen 1994). The age of cases showed a peak at 19 months, with 94% of cases less than 5 years of age. All ingestions were accidental and male cases outnumbered female cases by 1.5:1. Products based on NaOH or KOH accounted for 29% of cases. The incidence of cases of caustic ingestion decreased across the time period studies. This was ascribed to the introduction of measures such as child-proof caps on containers.

Israel

Records for cases admitted to the Hadassah Hebrew University Hospital, Jerusalem between 1988 and 2003 due to ingestion of caustic substances were reviewed (Arévalo-Silva et al 2006). Of the 50 cases identified, 25 were children under 5 years of age. All childhood cases involved accidental ingestion, while approximately two-thirds of the adult cases were attempted suicides. Alkaline substances were the most common agents involved. Injuries were more serious in cases of attempted suicide and incidents involving ingestion of acidic substances. Injuries to children were predominantly first degree (57%) or second degree (36%), with no fourth degree injuries.²

Europe (poisons centres)

An European risk assessment for sodium hydroxide reported experiences from several European poisons centres (European Chemical Bureau 2007).

Netherlands. Between 2000 and 2003, 272 accidents were reported. About 85% of cases were consumer accidents, with the majority involving drain openers (96%). Ingestion was the main route of exposure.

Belgium. During 2003, 277 sodium hydroxide exposures were reported. Exposures were mainly accidental (96%) and involved adults (88%). Dermal exposure was the main exposure route, with drain openers being a major cause.

Scotland. During the period 2000-2003, 112 cases were reported with 98% being accidental. Ingestion was the main exposure route. Drain cleaners were one of a range of causative substances.

Ireland. For the period 2000-2003, 222 incidents were reported following dermal or oral exposure to sodium hydroxide products, including drain openers.

– erythema with circumferential exudates, third degree – circumferential exudates, and fourth degree
 – circumferential exudates with oesophageal wall perforation

¹ It appears likely that this is a misspelling of 'chloridric acid', an alternative name for hydrochloric acid

² In this study oesophageal damage was graded as; first degree – mucosal erythema, second degree

Slovak Republic. A total of 37 incidents were reported during 2000-2003. All were accidental exposure by the oral route.

United Kingdom. During 2000-2002, 182 cases were reported with 73% being accidental exposure during consumer use. Dermal exposure was the main exposure route, with oven cleaners being the main caustic substance. Drain openers also contributed.

Switzerland. During 2000-2003, 295 cases were reported, with approximately equal proportions of occupational and consumer incidents. Dermal exposure was the main exposure route and drain openers one of the main causative substances.

Germany. In the period 1999-2003, 114 cases were report involving drain pipe cleaner or sodium hydroxide. The main exposure routes were oral and inhalation.

Across all poisons centres for which information was available, 41% of incidents were due to ingestion, 33% due to dermal exposure, 14% due to inhalation and 12% due to eye contact. It is uncertain whether these proportions would be consistent for drain cleaner and other substance related incidents. Only one centre (Belgium) provided age information, with the majority of incidents involving adults.

Summary

Ingestion of drainer cleaner does not appear to be a major cause of poisoning in New Zealand, with less than 0.3% of incidents collated in HSSS being definitely due to drain cleaner. Drain cleaner is not amongst the substances for which ingestion is most commonly queried through the New Zealand National Poisons Centre. No cases of mortality due to drain cleaner ingestion were reported for the period 2006-2009.

Internationally it has been noted that cases of serious harm (hospitalisation) due to caustic substance ingestion, including drain cleaner ingestion, is biphasic with cases less than 5 years of age being predominantly due to accidental ingestion in the home, while adult cases are predominantly due to intentional ingestion in suicide attempts.

2.2 Sodium Hydroxide (NaOH)

While other ingredients may be present in drain cleaner, only sodium hydroxide (NaOH) is present in all alkaline drain cleaners. Case reports suggest that the adverse health effects due to drain cleaner exposure are a consequence of exposure to NaOH (see section 2.1.3). The following sections on the risks associated with drain cleaner will focus on NaOH.

2.2.1 Previous Assessments

NaOH has previously been assessed by the European Chemical Bureau (ECB) (European Chemical Bureau 2007) and the Organization for Economic Cooperation and Development (OECD) (OECD-SIDS 2002).

Both assessments concluded that the major human health hazard of NaOH is local irritation and/or corrosion. NaOH is not expected to be systemically available in the body.

While NaOH is moderately acutely toxic by the dermal and oral routes of exposure, toxicity appears to be entirely due to the corrosive nature of the substance. NaOH is irritant or corrosive to the skin and eyes, depending on the concentration, but is not considered to be a skin sensitiser.

NaOH will neither reach the foetus nor reach male and female reproductive organs, which shows that there is no risk for developmental toxicity and no risk for toxicity to reproduction. Both *in vitro* and *in vivo* genetic toxicity tests indicated no evidence for a mutagenic activity.

The US Agency for Toxic Substances and Disease Registry (ATSDR) have also produced a summary factsheet on NaOH (ATSDR 2002). In addition to confirming that the main hazard due to NaOH exposure is irritation/corrosion, the fact sheet makes particular comment on the carcinogenic potential of NaOH. ATSDR concluded that while there have been reported of cancer of the oesophagus 15-40 years after corrosion due to NaOH (Appelqvist and Salmo 1980; Contini and Scarpignato 2013; Hopkins and Postlethwait 1981; Isolauri and Markkula 1989; Ti 1983), the cancers were most likely due to tissue destruction and scar formation, rather than as a result of carcinogenic action by NaOH.

2.2.2 Relevant recent toxicological studies

Scientific literature searches were carried out using search terms 'sodium hydroxide and the wildcard term 'toxic*'.

No relevant recent toxicological studies were found.

2.2.3 Observations in humans

Effects due to oral exposure

Solid NaOH is difficult to swallow and usually results in injury to the mouth and pharynx. Examination of 13 children who had sucked on granules of NaOH planted in a box of sweets revealed corrosive injury of the tongue and lips in two boys, but negative findings in the remaining 11 cases (Janoušek et al 2005).

Nine patients who ingested liquid NaOH were reviewed for location, extent, severity, and outcome of injury (Cello et al 1980). One person who ingested 10 g NaOH in water suffered transmural necrosis of the oesophagus and stomach and died three days after admission to the hospital. Assuming an adult male body weight of 70 kg, this equates to a dose of 142 mg/kg bw.

A 42-year-old female swallowed approximately 30 ml of 16% NaOH in a suicide attempt (Hugh and Meagher 1991). This resulted in a 9-cm stricture of the

esophagus which was treated by gastric antral patch esophagoplasty. Assuming an adult female weight of 65 kg, this equates to a dose of 74 mg/kg bw.

Effects on the skin

In human patch tests, NaOH was irritant at a concentration of 0.5% in 55-61% of test subjects (Griffiths et al 1997; York et al 1996). Application of NaOH (0.5 or 1.0%) to back skin for 3, 15 or 60 minutes resulted in increased erythema with increasing exposure time (Dykes et al 1995). Erythema continued to increase up to 48 hours post-application. Twenty-four hour patch testing with 4% NaOH produced reaction in all of 34 volunteers, but a distinction was possible between normal reactors (25/34) and hyper-reactors (9/34) (Seidenari et al 1995).

Effects on the eye

A study examined the epidemiology, management and outcome of 42 cases of alkali burns of the eye admitted to the eye clinic of the RWTH Aachen, Germany from 1985 to 1992 (Kuckelkorn et al 1993). The majority (74%) of cases involved industrial accidents. Of the home injuries, the majority were due to drain cleaners. Sodium and potassium hydroxide produced more extended and deeper damage than lime (calcium hydroxide) due to their rapid penetration through the ocular tissues. A delayed surgical intervention led to a longer time of stay in hospital and to a higher number of operations. All eyes could be prevented from melting (liquefying), but an optical rehabilitation (visual acuity >0.3) was achieved only in a few cases (14.5%).

An Australian study reviewed 12 cases of alkali burns involving the cornea (Bunker et al 2014). Most injuries were due to NaOH from 'trivial domestic accidents'. Ten of the 12 cases recovered fully, due to effective acute management. One case suffered cicatrical ectropian requiring surgical correction.

An Indian study stressed the need for effective acute management (Sharma et al 2012). In a case series of 16 ocular burns (31 eyes) due to NaOH, approximately 50% were graded as severe (grade VI on the Dua classification). Grade VI injuries had significantly worse recovery outcomes than the lower grades. While epithelial damage healed by 14 weeks, glaucoma (n = 7) and cataracts (n = 6) were the most common long-term complication. Other complications were seen mainly in the cases with grade VI injuries, including pseudopterygium (n = 5), scleral melting (n = 4), adherent leucoma (n = 2), trichiasis (n = 2), pyogenic granuloma (n = 2), anterior staphyloma (n = 2).

Effects on the respiratory tract

A case report was described of a 63 year old man, who had worked for 20 years cleaning large industrial jam containers with boiling NaOH solution (Rubin et al 1992). Clinical findings indicated severe obstructive airway disease. It was concluded that this condition was probably the result of irritation and burns to the respiratory system due to NaOH exposure.

In another case report, a formerly healthy 25-year-old developed irreversible obstructive lung injury after working for one day with a caustic soda (5%) treatment of wood in a poorly ventilated room (Hansen and Isager 1991).

A cross sectional survey of workers (n = 2404) in an Australian alumina refinery, exposed to NaOH mist, was carried out (Fritschi et al 2001). Exposure to caustic mists was assessed for different work areas using a semi-quantitative method. Areas were classified as low exposure (<0.05 mg/m³), medium exposure (0.05-1.0 mg/m³) or high exposure (>1.0 mg/m³). Workers in the highest current caustic exposure category had significantly higher prevalence of work-related wheeze and rhinitis than unexposed workers, but did not have measurable changes in lung function. Workers in the low and medium exposure groups did not have significantly greater prevalence of these respiratory conditions than unexposed workers. Peak NaOH levels were measured in the factory were less than 2 mg/m³.

3 DOSE-RESPONSE

There is no evidence that NaOH is systemically toxic and adverse health effects relate to local irritation and corrosion. Consequently, risk due to NaOH exposure will usually be a function of NaOH concentration, contact volume and contact time.

3.1 Oral and Dermal Exposure

Both exposure routes are concerned with the irritant or corrosive impact of NaOH on tissue. While there is potential for different tissue types to be more susceptible to the corrosive effects of NaOH, there is little evidence for this in the literature.

Studies on isolated rabbit oesophageal epithelium concluded that, while injury is both time and pH (concentration) dependent, a minimum pH of 11.5 (0.012% NaOH) was required for injury (Atug et al 2009). This is also the lower pH limit identified by NIOSH for dermal effects of NaOH and is probably an appropriate no observable adverse effect level (NOAEL) for oral or dermal exposure. On this basis, the European Chemical Bureau (ECB) classification for NaOH should be appropriate for dose-response assessment (European Commission 2014):

0.5-2.0%	Irritating to skin (R38)
2.0-5.0%	Causes burns (R34)
>5.0%	Causes severe burns (R35)

Animal and *in vitro* studies have demonstrated damage to the oesophageal epithelium at NaOH concentrations of 1.8–2.5% (Baskerville et al 2002; Henry et al 2008; Malvasio et al 2012). The severity of damage increases with increasing NaOH concentration.

Patch testing in humans demonstrated reaction by about half of subjects at NaOH concentrations of 0.5%, with all subjects reacting to 4% NaOH (Dykes et al 1995; Griffiths et al 1997; Seidenari et al 1995; York et al 1996). Patch testing uses quite small volumes of test material. For example, the Griffiths et al (1997) used 0.2 ml, applied to the small area of the upper arm. These studies varied considerably in the protocols used, with maximum contact times varying from 60 minutes (Dykes et al 1995) to 4 hours (Griffiths et al 1997; York et al 1996) to 24 hours (Seidenari et al 1995). In some studies patches were occluded (Griffiths et al 1997; York et al 1996), while in other studies there is no evidence that occlusion occurred (Dykes et al 1995; Seidenari et al 1995).

The annual reports of the American Association of Poison Control Centers' National Poison Data System contain case reports of some fatal chemical exposures. Case reports were reviewed for the period 2001-2013 for information relevant to NaOH ingestion. Descriptions of fatal doses included:

- Half a cup of alkaline drain cleaner (pH 13) (Bronstein et al 2008);
- 4-6 ounces (120-170 ml) of drain cleaner (Bronstein et al 2010); and
- 3 gulps of liquid drain cleaner (Bronstein et al 2011).

Unfortunately, none of the case studies give the concentration of NaOH in the drain cleaner. However, it appears that 100-200 ml of concentrated NaOH (probably of the order of 20%) can be fatal in some cases. Assuming a NaOH concentration of 20%

and using an adult body weight of 70 kg, 100-200 ml of drain cleaner equates to a dose of 285-570 mg/kg bw. Such a dose range for fatal consequence in humans is consistent with the LD₅₀ determined in rabbits of 325 mg/kg bw (OECD-SIDS 2002).

3.2 Eye Exposure

Studies in rabbits, in which 0.1 ml of NaOH solutions of various strengths were placed in the lower conjunctival sac of the left eye of rabbits, showed no irritant or corrosive effects at concentrations in the range 0.004-0.2% (Morgan et al 1987). Mild irritation was observed at 0.4% and corrosion at 1.2%.

In a rabbit low-volume (10 μ L) eye test, a 2% NaOH solution was associated with significant epithelial damage, but more limited corneal damage, while a 8% solution caused extensive injury (Jester et al 2000).

Based on the study of Morgan *et al.*, ECB adopted a NaOH concentration limit of 1.2% as a threshold for corrosive damage to the eye in their risk assessment of NaOH.

3.3 Inhalation Exposure

Respiratory exposure limit concentrations of 2 mg/m³ have been set for occupational exposure to NaOH (Centers for Disease Control and Prevention 1994; Worksafe New Zealand 2013). The same limit applies to ceiling (maximum) values and time weighted average (TWA) values. This is consistent with epidemiological evidence, which demonstrated a higher prevalence of work-related wheeze and rhinitis in workers exposed to >1 mg/m³ NaOH, but not at lower exposure levels (Fritschi et al 2001).

4 EXPOSURE ASSESSMENT

4.1 Exposure Scenarios for Sodium Hydroxide-based Drain Cleaners in New Zealand

The report considers domestic, non-occupational, routine and incidental exposure to household drain cleaner. Drain cleaner products available in New Zealand are in the form of crystals, liquid preparations or gels.

NaOH is non-volatile and correct use of drain cleaners does not including spraying, misting or any other mechanisms that will introduce the product into the air. It is assumed that use of these products will not lead to significant aerosolisation of NaOH and scenarios for inhalation exposure will not be considered.

It is also assumed that use of drain cleaners for their intended purpose is unlikely to result in oral exposure. Oral exposure by adults intending self-harm is also not included.

Three scenarios will be considered:

- Accidental oral exposure by children;
- Incidental dermal exposure by adults and children; and
- Incidental eye exposure by adults and children.

The latter two scenarios mainly relate to splash hazards during drain cleaning.

As NaOH is not systemically toxic, exposure doses were not estimated for the exposure scenarios defined in the following sections. Instead, the risk characterisation section involves a qualitative assessment of the likely adverse effects due to the exposure scenarios.

- 4.2 Accidental Oral Exposure by Children
- 4.2.1 Crystal (solid) drain cleaners

Crystal drain cleaner or solid NaOH is difficult to swallow and generally damage is restricted to burns of the lips, tongue and oral cavity (de Jong et al 2001; Janoušek et al 2005). In an incident involving 13 children who had sucked on granules of NaOH planted in a box of sweets, corrosive injury of the tongue and lips occurred in two boys, but negative findings in the remaining 11 cases (Janoušek et al 2005). It was concluded that in most cases the children spat out the granules before significant damage could occur.

Based on this information, no exposure scenario was considered for ingestion of solid drain cleaner.

4.2.2 Liquid or gel-based drain cleaners

NaOH in solution is odourless and tasteless and there appears to be few physical barriers to solutions of NaOH being swallowed. The introduction of liquid drain cleaners in the US in the late 1960s was reported to result in increasing numbers of

cases and increased severity of oesophageal lesions (Elshabrawi and A-Kader 2011).

In a case series of paediatric corrosive ingestion incidents in Turkey, ingested volumes were reported to be in the range 1 to 100 ml (Melek et al 2008).

While the concentration of NaOH in liquid or gel drain cleaners is lower (3-19% in products currently available in New Zealand) than that in crystal products, there is a greater potential for the corrosive material to be swallowed and cause damage to the oesophagus and the gastrointestinal tract.

A number of studies have found that ingestion of caustic substances mainly occurs in children aged 2-3 years (Casasnovas et al 1997; Christesen 1994; de Jong et al 2001; Melek et al 2008; Wiseman et al 1987). An exposure scenario was considered for this age group, for ingestion of drain cleaner containing 20% NaOH. Based on the study of Melek et al (2008), two volumes were assessed; a median volume of 50 ml and a high volume of 100 ml.

Scenario: Ingestion of a liquid drain cleaner (20% NaOH, ingestion volume 50 or 100 ml) by a 2-3 year old child.

4.3 Dermal Exposure

4.3.1 Adults

Scenario: ECB have presented a scenario for dermal exposure to NaOH from use of drain cleaner (European Chemical Bureau 2007). The scenario assumes personal protective equipment (PPE) is not used and that two drops of 50 μ L (0.05 ml) will end up on the skin of the hands. In line with the ECB risk assessment, it was assumed that dermal exposure to spatters when using pellets is comparable to that after using liquid drain openers.

Using the default thickness for the film on the skin given above ($T_{derm} = 0.01$ cm) each drop would equate to an area of 5 cm².

4.3.2 Children

No scientific literature information was found on the prevalence of child dermal injuries due to exposure to caustic substances. While there appears to be significant potential for children to sustain injuries due to spilling of crystal, liquid or gel-based drain cleaners on themselves, there is little evidence of this happening. A review of chemical burns treated at a Tasmanian hospital did not identify NaOH or drain cleaner as significant contributors to the burden of chemical burns (Ricketts and Kimble 2003).

Scenario: Based on this information, dermal exposure to drain cleaner by children was considered to be likely to be similar to exposure of adults.

4.4 Eye Exposure

A New Zealand study reported that the majority (82%) of chemical eye injuries were acquired in the workplace (Pandita and Merriman 2012). Chemical injuries to the eyes occurring at home (18%) were usually due to cleaning agents.

4.4.1 Adults

The ECB risk assessment did not consider eye damage due to normal consumer use of drain cleaner to be a relevant exposure pathway (European Chemical Bureau 2007). However, misuse of drain cleaner was recognised as having the potential to result in eye damage. A review of chemical eye injuries at an American eye hospital identified approximately 2% of injuries as due to drain cleaners (Blackburn et al 2012).

Scenario: Consumer eye exposure is likely to be of a similar magnitude to dermal exposure (see section 4.3.1), involving small volumes of concentrated NaOH.

4.4.2 Children

While there appears to be significant potential for children to sustain significant eye injuries due to splashing of liquid drain cleaners, there is little evidence of this happening. A study carried out in the United States, that identified drain cleaner as a causative agent in eye injuries, reported a mean age 32.8 years for household cleaning product-related injuries (Blackburn et al 2012).

While a number of studies have considered paediatric eye injuries, none were found that made specific mention of drain cleaner (Cao et al 2013; Chen et al 2013; El-Sebaity et al 2011).

Given the available information, it is not possible to speculate on the likely circumstances of child eye exposure to drain cleaner.

5 RISK CHARACTERISATION

The assessment for household drain cleaner was carried out in the context of incidental non-occupational exposures.

No systemic effects associated with NaOH exposure have been identified. Adverse effects on all tissue types relate to the local irritant or corrosive effects of this chemical. All NaOH-based drain cleaners available in New Zealand contain sufficient concentrations of NaOH to result in serious corrosion of affected tissues. Of the scenarios discussed, ingestion of liquid or gel drain cleaner by young children appears to have the greatest potential to result in serious injury (injury requiring on-going medical support). This conclusion is consistent with US experience, where the introduction of liquid drain cleaners resulted in an increase in the incidence and severity of injuries due to drain cleaner ingestion (Elshabrawi and A-Kader 2011).

Scenarios have been considered for ingestion of drain cleaner containing 20% NaOH by a child of 2-3 years. The concentration of NaOH in drain cleaner products is well above guidance concentrations at which severe burns would be expected (5.0%). Ingestion of 50 or 100 ml of liquid drain cleaner is likely to cause serious harm to young children, including corrosive damage to the mouth, oesophagus and the gastrointestinal tract.

Scenarios for ocular exposure involve small volumes of corrosive material. While there is potential for serious chemical burns, even at high NaOH concentrations (>30%) this level of exposure is only likely to affect very small areas of the eye.

Dermal exposures have been considered for minor splashes of drain cleaner containing 20% NaOH onto the skin of an adult or a child of 2-3 years. The concentration of NaOH in drain cleaner products is well above guidance concentrations at which severe corrosion would be expected (5.0%) and serious local effects are likely to result from dermal exposure.

Inhalation exposure is not considered to be likely for drain cleaner.

The exposure scenarios discussed here are speculative. Any exposure to drain cleaner products has the potential to cause serious harm, due to the concentrations of NaOH present in the products.

6 CONCLUSIONS

Hazards associated with exposure to drain cleaner products will be largely due to the high concentration of corrosive NaOH in these products. Products currently sold in New Zealand fall into two broad categories; crystals containing more than 50% NaOH and liquids or gels containing 3-19% NaOH.

There is no evidence that NaOH is systemically toxic and it occurs naturally in the body. NaOH is corrosive to all tissue types. The extent and degree of harm will be a function of the concentration of the hydroxide ion, the area affected and the contact time before removal or dilution. At low concentrations (0.5-2.0%), NaOH is an irritant. As the concentration increases, chemical burns occur, with the severity and depth of the burns increasing with NaOH concentration. The concentration of NaOH in drain cleaner products is well above guidance concentrations at which chemical burns will be expected to result (>2.0%) and for most drain cleaner products the concentration of NaOH is above guidance concentrations at which severe, irreversible damage from chemical burns would be expected (>5.0%). While there may be some limited capacity for human body fluids to dilute NaOH to non-corrosive concentrations, this should not be assumed. It should be considered that exposure of the skin, eyes or gastrointestinal tract to NaOH of sufficient concentration (>2.0%) has the potential to cause harm, irrespective of the volume of exposure.

Qualitative assessment of possible exposure scenarios suggests that the circumstance with the greatest probability of serious harm is ingestion of liquid or gel drain cleaner by young children (less than five years of age). Due to the sensitivity of the tissues involved and the difficulty of rapidly decontaminating the gastrointestinal tract, it must be assumed that harm may occur following ingestion of even the smallest volume of drain cleaner. Child-resistant measures on containers of these products are expected to mitigate the risk of injury and introduction of such measures in Denmark was related to a temporal decline in the incidence of caustic ingestion incidents in Denmark (Christesen 1994).

Surveillance of chemical injuries in New Zealand has not identified drain cleaner as a noticeable contributor. While there is potential for under-reporting (occurrence of injuries or incidents that do not come to the attention of the surveillance systems), unreported cases of drain cleaner injury will probably not be in the more severe categories.

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