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HEALTH RISK ASSESSMENT: FORMALDEHYDE AND HEAVY METALS IN FINGER PAINTS

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ABBREVIATIONS

ATSDR	Agency for Toxic Substances and Disease Registry
BMD	Benchmark dose
BMDL	Benchmark dose level
bw	Body weight
CSF	Cancer slope factor
DNEL	Derived no-effect level
ECHA	European Chemicals Agency
ESR	Environmental Science and Research Limited
EU	European Union
FA	Formaldehyde
FRP	Formaldehyde-releasing preservative
HBGV	Health-based guidance value
HM	Heavy metal
IARC	International Agency for Research on Cancer
IRIS	Integrated Risk Information System
LOAEL	Lowest observed adverse effect level
MET	Minimal elicitation threshold
MOS	Margin of safety
NOAEL	No observed adverse effect level
NPC	National Poisons Centre
NZ EPA	New Zealand Environmental Protection Authority
POD	Point of departure
PTMI	Provisional tolerable monthly intake

RCR	Risk characterisation ratio
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RfD	Reference dose
RIVM	Rijksinstituut voor Volksgezondheid en Milieu (National Institute for Public Health and Environment, Netherlands)
TDI	Tolerable daily intake
TWI	Tolerable weekly intake
UF	Uncertainty factor
US EPA	United States Environmental Protection Agency
WHO	World Health Organization

EXECUTIVE SUMMARY

The purpose of this report is to develop a generic health risk assessment for exposure to formaldehyde and heavy metals from the use of finger paints by children (up to 3 years of age). This report only considers domestic, non-occupational, incidental exposure to formaldehyde and heavy metals from this route of exposure. Exposure scenarios were developed for the most common or likely exposure events.

Finger paints are paste or jelly-like, coloured preparations specially designed for children. Finger paints can be applied directly to suitable surfaces with the fingers or hands. They are sold in several different colours within each brand. Finger paints generally contain water, colouring agents, fillers, binders, humectants, preservatives, surfactants and bittering agents, to discourage ingestion.

Some finger paints have been reported to contain high levels of heavy metals and formaldehyde. This has led to product recalls from the European market. However, no information was found on similar product recalls in New Zealand.

Few studies were found in the literature that have quantified formaldehyde and heavy metal concentrations in finger paints. The exact cause of heavy metal contamination of finger paints is not known but may be due to contaminated ingredients (mineral pigments) or manufacturing practices. Free formaldehyde is not intentionally added to finger paints but can be formed *in-situ* from formaldehyde-releasing preservatives such as DMDM hydantoin and quaternium-15 or due to alkaline hydrolysis of the preservative bronopol.

In New Zealand, finger paints are regulated as graphic materials by the New Zealand Environmental Protection Authority. Consequently, the regulation of finger paints is covered by the Graphic Materials Group Standard 2020 under the Hazardous Substances and New Organisms Act 1996. Finger paints must meet the conditions set out in the Graphic Materials Group Standard, which sets limits for the amounts of some heavy metals that can be leached from finger paints. Formaldehyde is not specifically mentioned in the Group Standard. By contrast, in Europe, finger paints are regulated as toys and must comply with the Toy Safety Directive 2009/48/EC. This directive sets migration limits of some metals from finger paints. In November 2019, the European Commission published two directives, (EU) 2019/1922 and 2019/1929, to update the European toy safety requirements. In the updated requirements, the limit for formaldehyde in water-based toy material such as finger paints is 10 mg/kg. There is little alignment between the New Zealand and European Union limits.

Children use finger paint by dipping their fingertips into the paint and making a painting on a suitable surface. Hence, exposure takes place through skin contact – primarily of the hands. Oral exposure is also possible, as children can swallow small amounts of finger paint. For exposure assessment, the maximum concentrations of HMs and FA provided in published studies and product recalls in the EU were used.

Dermal and oral exposure was estimated following exposure to heavy metals and formaldehyde. The total absorption of heavy metals and formaldehyde was then calculated as the sum of the dermal and oral absorption for 1 and 2-3 year old children.

Non-carcinogenic human health risks from exposure to heavy metals and formaldehyde in finger paints were evaluated by applying a margin of safety approach. It was found that while the margin of safety was more than 100 for chromium and nickel, it was less than 100 for

arsenic, cadmium, and lead. Formaldehyde is a cause for health concern in children with respect to non-cancer effects.

Two assessments that estimated the risk of heavy metals and formaldehyde in finger paints in other countries were also reviewed and summarised. Both assessments concluded that the potential oral intake of heavy metals and formaldehyde (0.1%) in finger paints did not constitute a health risk in children. However, these assessments used substantially lower concentrations of the contaminants in finger paints than were used in the current study. Additionally, one of these assessments used a tolerable daily intake value for risk characterisation of formaldehyde in finger paints, which is not the best practice for assessing carcinogens and genotoxic chemicals.

1. INTRODUCTION

The purpose of this report is to develop a generic health risk assessment for exposure to formaldehyde (FA) and heavy metals (HMs) from the use of finger paints by young children aged 3 and under. This report only considered domestic, non-occupational, incidental exposure to FA and HMs. Exposure scenarios were developed for the most common or likely exposure events.

Finger paints have many chemical ingredients that serve unique functions, such as preserving, colouring and maintaining stability of the product. Some of these chemical ingredients are banned or have restrictions in various countries. It is not possible to perform a risk assessment for each chemical, so a brief overview of the restrictions is provided in the regulatory section of this report.

1.1 CONSUMER PRODUCT DESCRIPTION – FINGER PAINTS

Finger paints are paste or jelly-like, coloured preparations specially designed for children, directly applicable to suitable surfaces with the fingers and hands (EPANZ, 2020; Garrigós *et al.*, 2001). These products have features such as bright colours, animals, and cartoon characters to attract the attention of children. Finger paints are sold in several different colours within each brand

Finger paints generally contain water, colouring agents, fillers, binders, humectants, preservatives, surfactants, as well as bittering agents to discourage ingestion (Garrigós *et al.*, 2001). The listed ingredients in one of the finger paints available in New Zealand include baking soda, citric acid, mannitol, polyethylene glycol (used for texture), sodium benzoate (used as a preservative), mineral oil and various food colourings (ehow, 2011).

1.2 FORMALDEHYDE AND HEAVY METALS IN FINGER PAINTS

1.2.1 Formaldehyde

FA is the smallest carbonyl compound. It is a colourless gas at room temperature with a strong odour, high volatility and high reactivity. Free formaldehyde is not intentionally added to finger paints but can be formed *in-situ* from formaldehyde-releasing preservatives such as DMDM hydantoin and quaternium-15 or due to alkaline hydrolysis of the preservative bronopol (Poulsen, 2014). These preservatives undergo hydrolysis and release small amounts of FA throughout the shelf-life of the product.

1.2.2 Heavy metals

Due to the ubiquitous and persistent nature of HMs, it is recognised that their presence as impurities and contaminants in products is unavoidable. HMs such as arsenic (As), aluminium (Al), cadmium (Cd), chromium (Cr), lead (Pb) and nickel (Ni) have been found in high concentrations in finger paints. The exact cause of elevated concentrations of HMs in fingerpaints is not known, but the presence of HMs in finished products can result from contaminated ingredients (mineral pigments) and manufacturing practices.

Several studies were found in the literature that have quantified FA and HM concentrations in finger paints. These are summarised in Table 1.

Table 1. Formaldehyde and heavy metal concentrations in finger paints

Survey country	Number of samples	Mean concentration (range) (mg/kg)	Reference
Formaldehyde			
Spain	5	633 (440-793)	(Garrigós *et al.*, 2001)
Spain	6	610	(Reche *et al.*, 2001)
Not reported	2	>1,000	(Wijnhoven *et al.*, 2008)
USA	1	201	(Sekerak, 2017)
Denmark	29	(20-70)	(Poulsen, 2014)
Heavy metals			
Iran	10	As: 0.38 (0.33-0.45) Cd: 6.76 (4.8-9.6) Cr: 9 (7.3-11) Pb: 50 (42-70)	(Baneshi *et al.*, 2023)
Turkey	7	Cu: 25.3 (<DL-144) Pb: 2.6 (1.7-3.7) Mn: 9 (4.5-13) ± 0.4 Cd: 0.83 (<DL-1.3) Co: <DL Ni: 3.5 (2.6-5.3)	(Erbas *et al.*, 2017)
Saudi Arabia*	11	As: 3.05 (0.2-8) Pb: 1.40 (0.4-5) Mn: 42.2 (1.42-372) Cd: 0.1 (0.05-0.2) Co: 4 (1-14) Ni: 5.2 (0.7-18.5)	(Khan *et al.*, 2021)
Denmark	57	Cd: <1 Cr: <1->10 Pb: <1->10	(Rasstogi, 1992)
Portugal	6	Pb: <DL Cd: 0.02 (<DL-0.03) Co: 0.12 (<DL-0.2) Cr: 0.25 (0.2-0.42) Ni: 0.8 (1.2-0.70) Mn: <DL Cu: 86 (<DL-338) Zn: <DL	(Rebelo *et al.*, 2015)

DL: detection limit, As: arsenic, Cd: cadmium, Co: cobalt, Cr: chromium, Cu: copper, Mn: manganese, Ni: nickel, Pb: lead, Zn: zinc

* Type of finger paint not specified.

1.3 REGULATION OF FINGER PAINTS

1.3.1 European union

1.3.1.1 Heavy metals

Finger paints are regulated as toys in the European Union (EU) and they must comply with the Toy Safety Directive 2009/48/EC (EU, 2009). This directive sets migration limits for certain HMs and other elemental contaminants from toys. Toy materials are divided into three categories: I. dry, brittle, powder-like or pliable toy material; II. liquid or sticky toy material; and III. scraped-off toy material. Finger paints fall under category II. The migration method for certain elements in toys is described in a harmonised standard, EN71-3 (current version EN71 Part3:2019+A1:2021). The maximum leachable limits in finger paints are presented in Table 2.

Table 2. Maximum leachable quantity limits of heavy metals for finger paints in the European Union

Element	Concentration limit (mg/kg)
Aluminium	1,406
Antimony	11.3
Arsenic	0.9
Barium	375
Boron	300
Cadmium	0.3
Chromium (III)	9.4
Chromium (VI)	0.005
Cobalt	2.6
Copper	156
Lead	0.5
Manganese	300
Mercury	1.9
Nickel	18.8
Selenium	9.4
Strontium	1,125
Tin	3,750
Tin – organic	0.2
Zinc	938

1.3.1.2 Formaldehyde

Toy Safety Directive 2009/48/EC (EU, 2009) also sets specific limit values for chemicals used in toys intended for use by children under 36 months of age or in other toys intended to be placed in the mouth. In November 2019, the European Commission published two directives, (EU) 2019/1922 and 2019/1929, to update the European toy safety requirements. In these updated requirements, the limit for FA in water-based toy material, which includes finger paints, is 10 mg/kg (EU directive, 2019).

The Toy Safety Directive also puts chemical restrictions on (EU, 2009):

1) preservatives
2) chemicals that are susceptible to cause cancer, change genetic information, harm fertility or harm an unborn child (so-called CMR substances)
3) 55 allergenic fragrances that have been banned, although some of these, as well as 11 additional fragrances, may be used in certain toys provided that they are indicated on the label and comply with additional requirements.

1.3.2 Australia

Finger paints are also regulated as toys in Australia and must comply with the applicable Australian mandatory safety standards (ACCC, 2024). Consumer Protection Notice No. 1 of 2009 sets out the mandatory requirements for toys and finger paints as prescribed. Finger paints supplied to Australia must not contain migration levels in excess of the levels listed in Table 3.

Table 3. Maximum leachable quantity limits of heavy metals for finger paints in Australia

Element	Maximum leachable quantity (mg/kg)
Antimony	10
Arsenic	10
Barium	350
Cadmium	15
Chromium	25
Lead	25
Mercury	10
Selenium	50

1.3.3 New Zealand

In New Zealand, finger paints are regulated as graphic materials by the New Zealand Environmental Protection Authority (NZ EPA). Consequently, the regulation of finger paints is covered by the Graphic Materials Group Standard 2020 under the Hazardous Substances and New Organisms Act 1996. Finger paints must meet the conditions set out in the Graphic Materials Group Standard.

The Group Standard sets limits for the amounts of some HMs that can be leached from finger paints, as shown in Table 4.

Table 4. Maximum leachable quantity limits of heavy metals for finger paints in New Zealand

Element	Maximum leachable quantity (mg/kg)
Antimony	60
Arsenic	25
Barium	250
Cadmium	50

Chromium	25
Lead	90
Mercury	25
Selenium	500

The Group Standard does not, however, provide any information on the restriction of other chemicals (preservatives, colourants, etc.) or impurities, including FA.

It is evident from the information provided above that the EU and Australia enforce lower and stricter migration limits for HMs than New Zealand. Additionally, no restriction limits could be found for FA or FRPs in finger paints in New Zealand or Australia. It is worth noting that Ni, a known skin sensitiser, has no migration limits for finger paints in New Zealand.

1.4 PRODUCT RECALLS OF FINGER PAINTS

The European Commission Safety Gate[1] is used by EU market surveillance authorities to notify Member States about unsafe and noncompliant non-food products, including those that present a risk to the health and safety of consumers. The online system serves as a single rapid alert system for dangerous consumer products. All non-food products that are intended for consumers or likely to be used by consumers under reasonably foreseeable conditions are included within the scope of this online system, with the exception of pharmaceutical and medical products.

The Safety Gate alert system contained 33 alerts or recalls for various finger paint products due to the presence of FA, HMs or other chemicals between January 2014 and July 2024. All the products recalled were non-compliant with the requirements of the Toy Safety Directive and the European standard EN 71-7. Examples of the types of products that have been recalled are provided in Table 5.

Table 5. Summary of European Commission rapid alert system for non-food dangerous products (RAPEX) alerts for formaldehyde and heavy metals in finger paint

S.no	Recalled product	Year	Reason
Formaldehyde			
1	Crayola, 4 tubes de peinture aux doigts lavables	2023	Up to 720 mg/kg
2	Alpino, My first finger paints – mis primeras pinturas	2023	Up to 2,500 mg/kg
3	Finger paint kit	2023	Up to 140 mg/kg
4	Hema, Peinture à doigts	2023	Up to 7,255 mg/kg
5	Magic Do – Tiger Zhou, finger paints	2023	Up to 958 mg/kg
6	Paint stamp	2023	Up to 510 mg/kg
7	Jovi, Finger paint	2023	Contains formaldehyde
Heavy metals			

[1] https://ec.europa.eu/safety-gate-alerts/screen/search?resetSearch=true

S.no	Recalled product	Year	Reason
1	Mokeelo, Peinture doigt gouache enfant palette; 12 × Peinture doigt pour bébé et enfant nettoyage à l'eau	2022	Excessive migration of aluminium and copper (up to 2,612 mg/kg and 296 mg/kg, respectively)
2	Nova Color, Finger paint FATIH 25 mL, 6 colours	2021	Excessive migration of lead in the white paint (measured value = 11,800 mg/kg)
3	Kohinoor, finger colours – prstové barvy	2016	Aluminium (measured value = 265,000 mg/kg) and the red colour contains cobalt (measured value = 2,629 mg/kg)
4	Vivabook, Tinta para pintar com os dedos ('Finger paint')	2015	Lead (measured value = 4.52 mg/kg)

2. HAZARD IDENTIFICATION

2.1 PREVIOUS ASSESSMENTS

No previous health impact assessments for finger paints were found for New Zealand. However, risk assessments on finger paints in other countries have been published by Poulsen (2014) and Rebelo *et al.* (2015). Both these studies assessed the potential metal intake of children after ingestion of and dermal contact with finger paints. The results of both the risk assessments are summarised in section 5 of this report.

2.2 HEALTH EFFECTS – INCIDENT SURVEILLANCE IN NEW ZEALAND

The National Poisons Centre (NPC) was contacted to provided surveillance information on reported exposures to finger paints. The NPC confirmed that it does not collect exposure data on finger paints from callers (William Boroughf, National Poisons Centre, personal communication). The most common call it receives in relation to paints is with respect to children ingesting craft paints, which is of little acute consequence in nearly every case. The NPC also does not receive calls related to the effects of the components of paints or inks.

2.3 TOXICITY

The toxicity of FA and HMs has been extensively reviewed by several authorities, such as the International Agency for Research on Cancer (IARC), Agency for Toxic Substances and Disease Registry (ATSDR), United States Environmental Protection Agency (US EPA), and European Chemicals Agency (ECHA). Previous health risk assessments by Environmental Science and Research Limited (ESR) have also discussed the toxicology of HMs and FA in tattoo inks and laminated flooring, respectively (Curtis, 2020; Gautam, 2023). Hence, the toxicology of HMs and FA are only briefly summarised below based on information provided in respective reports.

2.3.1 Heavy metals

2.3.1.1 Arsenic (As)

Most of the toxicology data available on As is for industrial workers (ATSDR, 2007). Acute oral exposure to lower levels of As has resulted in effects on the digestive tract (constriction of the throat, dysphagia, nausea, vomiting, watery diarrhoea), respiratory tract (respiratory distress, haemorrhagic bronchitis), central nervous system (encephalopathy, weakness, delirium), cardiovascular system (hypotension, shock), liver (increased enzymes and size) and blood (anaemia, leukopenia).

Chronic oral exposure of humans to elevated levels of inorganic As has been associated with effects on the gastrointestinal system, blood, skin, eyes, lungs, heart, central nervous system, liver and kidneys. Such effects include anaemia, peripheral neuropathy, skin lesions, hyperpigmentation, gangrene of the extremities, vascular lesions and liver or kidney damage.

IARC has determined that inorganic As is carcinogenic to humans (Group 1), and the US EPA has also classified inorganic As a human carcinogen (Group A) via the inhalation and oral routes (ATSDR, 2007; IRIS, 1991b). This classification is based on the inhalation of As-containing particulates by workers in occupational settings (smelters, coal-fired power plants, battery assembly, glass manufacturing and the electronics industry). IARC estimated that approximately 25% of daily dietary As intake is from inorganic sources.

2.3.1.2 Cadmium (Cd)

Acute toxicity data for Cd in humans are very scarce and there are no reliable human studies following acute-duration oral exposure. Acute exposure to high doses of Cd in laboratory animals results in a variety of effects, including altered haematological parameters, focal necrosis and degeneration of the liver, focal necrosis in renal tubular epithelium, necrosis and ulceration in the stomach and intestines, decreased motor activity, and testicular atrophy and necrosis.

Cd is primarily toxic to the kidneys and bones after repeated exposure in animals and humans (EFSA, 2009). Chronic exposure to Cd via the oral or inhalation routes has produced proximal tubule cell damage, proteinuria, glycosuria, amino aciduria, polyuria, decreased absorption of phosphate, and enzymuria in humans and a number of laboratory animal species. The renal damage caused by Cd is often cumulative and has been related to the lifetime Cd dose, and episodic exposures at any age contributes to a person's lifetime accumulated Cd exposure and therefore risk.

IARC has classified Cd as a human carcinogen (Group 1) based on animal and occupational studies and concluded that "there is sufficient evidence in humans for the carcinogenicity of cadmium and cadmium compounds" (IARC, 1993). Cd and Cd compounds cause cancer of the lung and have also been associated with cancer of the kidney and prostate.

2.3.1.3 Lead (Pb)

Studies of Pb exposure in humans as well as laboratory animals have reported effects on the nervous, cardiovascular, renal, immune, haematological and reproductive systems, developmental effects, and an increased incidence of cancer (EFSA, 2010; JECFA, 2011). There are no health-based guidance values for Pb as there is no evidence of thresholds for a number of critical health effects (developmental neurotoxicity in young children and cardiovascular effects and nephrotoxicity in adults). Hence, there is no level of exposure that is considered safe.

The acute toxicity of Pb is low, but the ingestion of large amounts of Pb can produce gastrointestinal symptoms, including colic, constipation, abdominal pain, anorexia and vomiting (JECFA, 2011).

The critical effects that occur as a result of exposure to Pb include developmental neurotoxicity in young children and cardiovascular and kidney effects in adults, with changes in the systolic blood pressure and the prevalence of chronic kidney disease being the critical endpoints in adults.

Exposure to Pb during pregnancy has been associated with toxic effects on the human foetus, including an increased risk of preterm delivery, low birth weight and impaired mental development, such as decreased IQ scores (ATSDR, 2020).

Human studies are inconclusive regarding the association between Pb exposure and other birth defects, but animal studies have shown a relationship between high Pb exposure and birth defects (CDC, 2012).

Human studies are also inconclusive regarding the relationship between Pb exposure and cancer risk. However, animal studies have reported kidney tumours in rats and mice exposed to Pb via the oral route. Consequently, IARC has classified inorganic Pb compounds as probably carcinogenic to humans (IARC, 2006b).

2.3.1.4 Nickel (Ni)

The main human health effects of concern associated with Ni exposure include Ni allergic contact dermatitis, respiratory carcinogenicity, reproductive toxicity, immunotoxicity and non-cancer respiratory effects. Acute ingestion of Ni compounds may cause nausea, vomiting, diarrhoea, headache, cough and shortness of breath. In severe cases, ingestion of large amounts of Ni compound may cause death. Chronic oral exposure to Ni or Ni compounds has not been characterised in humans (ATSDR, 2005).

Ni is of low acute toxicity via the oral route in animals. Generally, soluble Ni compounds are more toxic than insoluble compounds – for instance, single-dose oral lethality studies have indicated that soluble Ni compounds are acutely toxic to rats whereas less soluble or insoluble Ni compounds are not acutely toxic to rats.

Some forms of Ni may be acutely toxic to humans in large doses. Acute inhalation exposure of humans to Ni compounds may produce headache, nausea, respiratory disorders and death. Asthmatic symptoms have also been documented following inhalation exposure to Ni compounds.

Ni is a well-known skin sensitiser, and allergic contact dermatitis is a commonly reported effect of exposure to Ni in humans. Exposure through the skin or airways may lead to Ni sensitisation, with the type of sensitisation being associated with the route of exposure. The combination of Ni with circulating or tissue protein gives rise to new antigens and acts as a contact allergen and causes sensitisation.

IARC concluded that there is sufficient evidence in humans for the carcinogenicity of mixtures that include Ni compounds and Ni metal. These agents cause cancers of the lung and of the nasal cavity and paranasal sinuses. Consequently, Ni compounds are classified as carcinogenic to humans (Group1) via the inhalation route (IARC, 1990).

2.3.1.5 Chromium (Cr)

Cr occurs in the environment primarily in two valence states: trivalent Cr [Cr III)] and hexavalent Cr [Cr (VI)]. Cr (III) is much less toxic than Cr (VI).

Acute oral toxicity in humans has been studied after intentional or accidental poisoning at high doses of Cr (VI), with the sources of Cr (VI) including chromic acid, potassium chromate and ammonium dichromate. Clinical effects of the high-dose poisoning in humans included haematological, hepatic and renal injury (EFSA, 2014).

In humans, acute dermal exposure to Cr (VI) causes chrome holes or chrome ulcers (i.e. skin burns, blisters and skin ulcers). Necrosis and sloughing of the skin at the site of application of a salve containing potassium chromate have also been reported in individuals (ATSDR, 2012).

Cr (VI) compounds can cause serious eye irritation. The severity of response is increased by a low pH or high temperature. In humans, accidental splashing of highly water-soluble Cr (VI) compounds in solution into the eye has resulted in damage (ATSDR, 2012).

Cr (VI) compounds (sodium/potassium dichromate) are highly hydrophilic and have been found to be skin sensitisers in the modified guinea pig maximisation test and the mouse ear swelling test. Cr (VI) is also reported to cause contact allergic dermatitis in sensitive individuals. It has been reported that at concentrations of 0.5% and below, potassium dichromate elicited a response in patch testing studies (EFSA, 2014).

Cr (VI) compounds have been evaluated by several IARC working groups in different years. IARC concluded that there was sufficient evidence in humans for the carcinogenicity of Cr (VI) compounds with respect to cancer of the lung and cancer of the nose and nasal sinuses from occupational studies. There was also sufficient evidence in experimental animals for the carcinogenicity of Cr (VI) compounds. Therefore, Cr (VI) compounds are classified as carcinogenic to humans (Group 1). The US EPA has also proposed that Cr (VI) is “likely to be carcinogenic by oral route” (USEPA, 1998).

2.3.2 Formaldehyde

FA is a small, reactive carbonyl with a significant vapour phase that interacts with proteins, DNA and RNA (Curtis, 2020). The interaction with proteins results from combination with primary amide bonds and the amino groups. FA also reacts with carboxyl, sulfhydryl and hydroxyl functional groups. These chemical interactions may result in altered nucleic acid (i.e. mutations) and protein qualities (i.e. the forming immunogenic protein derivatives) that have implications for mutagenesis and allergy, respectively, and can be highly irritating to the upper respiratory tract.

The non-cancer adverse health effects of FA are largely due to its ability to irritate mucous membranes of the eyes and upper respiratory tract. As a result of its solubility in water and high reactivity, FA is efficiently absorbed into the mucous layers protecting the eyes and respiratory tract, where it rapidly reacts, leading primarily to localised irritation. Acute high exposure may lead to eye, nose and throat irritation, as well as nasal obstruction, pulmonary oedema and dyspnoea following exposure in the respiratory tract. Prolonged or repeated exposures have been associated with allergic sensitisation, respiratory symptoms (coughing, wheezing, shortness of breath), histopathological changes in the respiratory epithelium and decrements in lung function. Children, especially those with asthma, may be more likely to show impaired pulmonary function and symptoms than adults following chronic exposure to FA (ATSDR, 1999).

Chronic inhalation of high concentrations of FA has been shown to be carcinogenic, inducing a high incidence of nasal squamous cell carcinomas in rats. Some epidemiologic studies have also found increased incidence of nasopharyngeal carcinoma and leukaemia in humans exposed to FA. There is sufficient evidence that FA can cause nasopharyngeal cancer and leukaemia in humans, so IARC has classified FA as carcinogenic to humans (Group 1) (IARC, 2006a).

Some animal studies have evaluated the carcinogenicity of FA after oral exposure, and an increased tumour incidence has been observed in some cases (Monakhova *et al*., 2012; Soffritti *et al*., 2002). However, all these studies had major limitations, making it difficult to interpret the results with confidence. There is little direct evidence of the carcinogenicity of FA following oral and dermal exposure.

3. DOSE-RESPONSE INFORMATION

Finger paints are generally used by children aged 1 to 3 years. Thus, exposure to FA and HMs from finger paints (e.g. when mouthed) is characterised by daily exposure during a maximum period of 1-2 years. In toxicological terms, this represents sub-chronic exposure. However, health-based guidance values (HBGVs) for sub-chronic exposure are not generally available for chemical substances. However, HBGVs from oral chronic toxicity studies on the other hand are routinely available for most chemical substances. Using a chronic HBGV also assures an adequate level of protection because HBGVs generally decrease in magnitude as the time frame being considered increases.

A point of departure (POD) is defined as the point on a toxicological dose-response curve established from experimental or observational data that generally corresponds to an estimated low effect level or no effect level. It marks the beginning of extrapolation to the toxicological reference dose (RfD) or tolerable daily intake (TDI). The most commonly used PODs are the no observed adverse effect level (NOAEL), the lowest observed adverse effect level (LOAEL) and the benchmark dose (BMD) for a defined level of response.

The BMD approach is preferred as the dose descriptor for the PoD as it has distinct advantages over the NOAEL approach in that the modelled BMD (BMD_{05} or BMD_{10}) reflects the shape of the dose–response curve and is less affected by the choice of experimental concentrations in the underlying toxicological study. However, the BMD approach requires a robust data set and additional knowledge of statistical modelling. When no BMD can be calculated or is available, NOAEL or LOAEL values are usually applied.

3.1 NON-CANCER EFFECTS

A RfD and TDI are HBGVs used in non-cancer health assessments. A RfD or TDI is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral or inhalation exposure for a chronic duration (up to a lifetime) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime (US EPA, 1993).

The PODs and HBGVs used in the current study for the characterisation on risks associated with exposure to HMs and FA in finger paints are summarised in Table 6. Where HMs have multiple PODs, the values in bold were used for this risk assessment.

Table 6. Health-based guidance values for heavy metals and formaldehyde

Study / key effect	POD	UF	HBGV	Reference
Arsenic				
Human chronic oral exposure / hyperpigmentation, keratosis and possible vascular complications	NOAEL: 0.0008 mg/kg bw/day	3	RfD: 0.0003 mg/kg bw/day	(IRIS, 1991b)
Cadmium				
Human studies involving chronic exposure /	**NOAEL (water):** **0.005 mg/kg/day**	10	RfD: 0.0005 mg/kg bw/day (0.5 µg/kg bw/day)	(IRIS, 1989)

Study / key effect	POD	UF	HBGV	Reference
significant proteinuria				
Meta-analysis of human studies / urinary cadmium levels and beta-2-microglobulin	1 μg cadmium/g creatinine	Not required	TWI: 0.0025 mg/kg bw (2.5 μg/kg bw, equivalent to 0.36 μg/kg bw/day)	(EFSA, 2009)
Meta-analysis of human studies / urinary cadmium levels and beta-2-microglobulin	NOAEL: 5.24 μg/g creatinine	-	PTMI: 25 μg/kg bw/month, equivalent to 0.82 μg/kg bw/day	(JECFA, 2011a)
Chromium				
Rat, 1-year drinking water study / no effects observed	NOAEL: 25 mg/L chromium as K_2CrO_4 2.5 mg/kg bw/day (adj.)	900	RfD: 0.003 mg/kg bw/day (3 μg/kg bw/day)	(IRIS, 1998)
Lead				
Meta-analysis of neurodevelopment studies (children) / decrease of 1 IQ point in children	$BMDL_{01}$: 0.0006 mg/kg bw/day (0.6 μg/kg bw/day)	-	-	(WHO/FAO, 2011)
Nickel				
Rat chronic oral study / decreased body and organ weights	**NOAEL: 5 mg/kg/day**	300	RfD: 0.02 mg/kg bw/day (20 μg/kg bw/day)	(IRIS, 1991a)
One- and two-generation studies in rats / increased incidence of post-implantation loss	$BMDL_{10}$: 1.3 mg Ni/kg	100	TDI: 0.013 mg/kg/day (13 μg/kg bw/day)	(EFSA, 2020)
Formaldehyde				
Rat 2-year bioassay / reduced weight gain, histopathology	NOAEL: 15 mg/kg bw/day	100	RfD: 0.2 mg/kg bw/day	(IRIS, 1990)

POD: point of departure, UF: uncertainty factor, HBGV: health-based guidance value, NOAEL: no observed adverse effect level, RfD: reference dose, TWI: tolerable weekly intake, PTMI: provisional tolerable monthly intake, LOAEL: lowest observed adverse effect level, bw: body weight, BMDL: benchmark dose level, TDI: tolerable daily intake

4. EXPOSURE ASSESSMENT

For chronic exposure estimation, selection of the concentration of chemical to be used in the exposure calculation is a key variable. The limited number of studies that have quantified levels of HMs and FA (see Table 1) and the product recall data shown in Table 5 were considered when selecting the concentrations to include in the exposure assessment of finger paints. A conservative decision was made to use the maximum reported concentrations to provide a 'worst-case' scenario for the assessment of risks. While this may be an unrealistic approach over the long term, brand loyalty means that individuals may be repeatedly exposed to a product with undesirable properties.

The following HM concentrations were selected for the exposure estimation based on published studies and product recalls: Pb, 11,800 mg/kg; As, 3.05 mg/kg; Cd, 6.76 mg/kg; Cr, 9 mg/kg; and Ni, 3.5 mg/kg (Baneshi *et al.*, 2023; Erbas *et al.*, 2017). In terms of FA, product recalls in the EU provide recent data on FA levels detected in finger paints, so a concentration of 7,255 mg/kg was selected for the exposure estimation in young children.

4.1 RELEVANT EXPOSURE SCENARIOS

The relevant exposure scenarios are dependent on the usage of the products. As the name suggests, while using finger paints, children dip their fingertips into the paints and make a painting on a suitable surface. Hence, exposure takes place through skin contact – primarily of the hands. Children (1- 3 year age) can also unintentionally swallow small amounts of finger paints by licking their fingers. Exposure is also possible from direct ingestion. The risks to children of more than 3 years of age are negligible as incidental ingestion or oral exposure is not expected. Inhalation exposure is unlikely as finger paints are water-based products.

The exposure routes considered in this assessment are summarised in Table 7.

Table 7. Exposure routes considered for formaldehyde and heavy metals in finger paints

Population	Product type	Exposure pathway		
		Inhalation	Dermal	Oral
Children (2 - 3 years)	Finger paint		X	X

4.2 EXPOSURE CALCULATIONS AND TIERED APPROACH

The exposure to FA and HMs while using finger paints was estimated according to the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) guidance on consumer exposure, the Dutch National Institute for Public Health and Environment (Rijksinstituut voor Volksgezondheid en Milieu; RIVM) guidance on chemical safety of toys with a focus on elements, and the ConsExpo Children's Toys Fact Sheet (Bremmer and Van Veen, 2002; ECHA, 2016).

4.2.1 Dermal scenario: Instant application of a substance contained in a mixture

A Tier I worst-case approach was taken, as an amount of finger paint is applied on the skin and thereby can potentially be absorbed through the skin (ECHA, 2016; Poulsen, 2014). Dermal exposure (Dexp) was calculated using the following equation:

$$\mathrm{Dexp} = \frac{Q(\mathrm{prod}) \times C \times \mathrm{n} \times \mathrm{Dap}}{\mathrm{BW}}$$

where *Q*(prod) is the quantity of product used, *C* is the concentration of chemical in the product, Dap is the dermal absorption and BW is the mean body weight of a child (see Table 8).

Table 8. Parameters used in the dermal exposure assessment

Parameter	Value	Reference
Dexp is the dermal exposure or dermal dose, i.e. the amount of substance that can potentially be taken up per kg body weight; later is accounted for the actual dermal rate of absorption of the substance	-	-
Q(prod) is the amount of product used	20 g; it was assumed that all the finger paint that is used each time ends on the skin and is accessible for dermal absorption	(Bremmer and Van Veen, 2002; Poulsen, 2014)
C is the concentration of chemical in finger paint (mg/kg)	As: 3.05 Cd: 6.76 Cr: 9 Ni: 3.5 Pb: 11,500 FA: 7,255	-
Dap is the dermal absorption (%)	HMs: 1 FA: 5	HMs: conservative value FA: (Bartnik *et al.*, 1985)
n is the mean number of exposure events per day	45 minutes per day, 100 times per year, which equates to 100/365 = 0.274 events/day	(Bremmer and Van Veen, 2002; Poulsen, 2014)
BW is the mean body weight of a child	1 year old: 9.65 kg 2-3 year old: 15.2 kg	(Cressey, 2016)

As: arsenic, Cd: cadmium, Cr: chromium, Ni: nickel, Pb: lead, FA: formaldehyde, HM: heavy metal

The dermal absorption of HMs through the skin was calculated to be 0.05% to 1%. Therefore, for the exposure assessment of finger paints in children, a conservative value of 1% was assumed.

4.2.2 Oral scenario: exposure to a substance in a product during normal use

Finger paints are available in many colours, which can be aesthetically appealing to young children. Therefore, they can swallow small amounts of finger paint. The oral intake of a substance being swallowed can be calculated by the following equation (ECHA, 2016; Poulsen, 2014):

$$\mathrm{Oexp} = \frac{Q\ (\mathrm{prod\ ing}) \times\ C \times \mathrm{n}\ \times \mathrm{Abs}}{\mathrm{BW}}$$

where *Q*(prod ing) is the quantity of product ingested, *C* is the concentration of chemical in the product, Abs is the oral absorption and BW is the mean body weight of a child (see Table 9).

Table 9. Parameters used in the oral exposure assessment

Parameter	Value	Reference
Oexp is the Intake per day	-	-
Q (prod ing) is the amount of product being swallowed	400 mg	(SCHER, 2016)
C is the concentration of chemical in finger paint (mg/kg)	As: 3.05 Cd: 6.76 Cr: 9 Ni: 3.5 Pb: 11,500 FA: 7,255	-
Abs is the oral absorption (%)	As: 100 Cd: 6 Cr: 7 Ni: 10 Pb: 60 FA: 100	(Chain *et al.*, 2020; EFSA, 2010; SCHER, 2015)
n is the mean number of events per day	45 minutes per day, 100 times per year, which equates to 100/365 = 0.274 events/day	(Bremmer and Van Veen, 2002; Poulsen, 2014)
BW is the mean body weight of a child	1 year old: 9.65 kg 2-3 year old: 15.2 kg	(Cressey, 2016)

As: arsenic, Cd: cadmium, Cr: chromium, Ni: nickel, Pb: lead, FA: formaldehyde

According to the exposure scenario for finger paints in the Children's Toys Fact Sheet (Bremmer and Van Veen, 2002), an 18-month-old, 9.85 kg child plays with finger paints 100 times per year for an average of 45 min it is assumed that 30 mg/min of finger paint is swallowed per minute through hand-to-mouth contact, which results in a total ingestion of 1,350 mg per play event (45 minutes × 30 mg/min). Since finger paints in New Zealand generally contain bitter substances, an oral intake of 400 mg was assumed for children up to 3 years of age based on the opinion of SCHER (2016) on liquid/sticky toy materials instead of the 1,350 mg suggested by RIVM.

4.2.3 Exposure outputs

The exposure calculations for HMs and FA are presented in Table 10 as per the calculation methods stated in the previous section. Values are calculated for oral and dermal exposure for children aged 1 year and 2-3 years. The total absorption of HMs and FA for each category was calculated as the sum of the dermal and oral absorption.

Table 10. Exposure values for heavy metals and formaldehyde

Heavy metal / chemical	Concentration	1 year old child			2-3 year old child		
		Oral exposure (mg/kg bw/day)	Dermal exposure (mg/kg bw/day)	Total exposure (dermal + oral; mg/kg bw/day)	Oral exposure (mg/kg bw/day)	Dermal exposure (mg/kg bw/day)	Total exposure (dermal + oral; mg/kg bw/day)
Arsenic	3.05	3.41E-05	1.70E-05	5.12E-05	2.10E-05	1.10E-05	3.10E-05
Cadmium	6.74	4.52E-06	3.76E-05	4.22E-05	3.0E-06	2.42E-05	2.72E-05
Chromium	9	7.04E-06	5.03E-05	5.74E-05	4.54E-06	3.24E-05	3.70E-05
Nickel	3.5	4.0-06	2.0E-05	2.35E-05	2.52E-06	1.26E-05	1.51E-05
Lead	11,800	0.08	0.06	0.14	0.05	0.04	0.09
Formaldehyde	7,255	0.08	0.20	0.30	0.05	0.13	0.18

bw: body weight

5. RISK CHARACTERISATION

Finger paints are used by children from the age of 1 to 3 years on average 100 times per year for 45 minutes per play event (Poulsen, 2014; Van Engelen *et al.*, 2015). The use of any product for only 2 years is generally considered sub-chronic exposure, so chronic exposure to the chemicals in finger paints is not expected.

Some of the HMs (As, Cd, Cr, and Ni) are known human carcinogens, but this classification is based on incidences of cancer following inhalation exposure in occupational settings where workers (in smelters, refinery, battery-producing industry, pigment production, and chromium plating) are exposed to HMs at very high concentrations in the form of dust, powder, or fumes. As is also reported with the increase incidences of cancer through ingestion of drinking water, but at high concentrations over prolonged periods of time. This level of exposure to HMs is not expected in children (2-< 3 years of age) from the use of finger paints. Therefore, a carcinogenic risk assessment is not possible.

FA is a known carcinogen through inhalation route under conditions of unusually high or prolonged exposure. High levels of FA are not expected to be present in finger paints. Exposure to FA through finger paints is expected only to take place either through dermal contact or oral ingestion. There is little direct evidence of the carcinogenicity of FA following oral and dermal exposure. FA is highly volatile and can evaporate rapidly thereby enabling inhalation of the substance. However, this level is expected to be very low and the contribution to carcinogenic risk is consequently low. There are some studies in the literature that have evaluated the carcinogenicity of FA after oral exposure and have major limitations that make it difficult to interpret the results with confidence. There is little direct evidence of the carcinogenicity of FA following oral and dermal exposure. Therefore, the contribution of FA to carcinogenic risk is likely to be low.

Hence, non-cancer risk assessment following oral and dermal exposure is only performed for HMs and FA in finger paints.

5.1 NON-CANCER RISK

A margin of safety (MOS) approach was used to assess the expected level of safety in relation to non-cancer effects associated with HMs and FA in finger paints. MOS is the ratio between a systemic POD (PODsys, which is usually the NOAEL or BMD values from oral studies) and an estimate of the systemic exposure (SCCS, 2021) and is calculated as:

$$\mathrm{MOS} = \frac{\mathrm{PODsys}}{\mathrm{Exposure}}$$

The BMD approach is preferred as the dose descriptor for the POD and MOS calculations, as outlined in section 3. However, when no BMD can be calculated or is available, NOAEL values are usually applied. If a BMD or a NOAEL cannot be identified from the available data, other PoDs such as the Lowest Observed (Adverse) Effect Level (LOAEL) may be used in the MoS calculation.

For a chemical substance with health thresholds (i.e, that is not genotoxic or carcinogenic), a MOS ≥ 100 is generally considered to be protective. The MOS values calculated in the current assessment are presented in Table 11.

Table 11. Margin of safety values for heavy metals and formaldehyde in finger paints

Heavy metal / chemical	Total exposure (mg/kg/day)		PODsys (mg/kg bw/day)	MOS	
	1 year old	2 - 3 year old		1 year old	2 - 3 year old
Arsenic	5.12E-05	3.10E-05	NOAEL: 0.0008	15.64	24.25
Cadmium[a]	4.22E-05	2.72E-05	NOAEL: 0.005 x 0.06 = 0.0003	7.11	11.02
Chromium[b]	5.74E-05	3.70E-05	NOAEL: 2.5 x 0.07 = 0.17	3050	4731
Nickel[c]	2.35E-05	1.51E-05	NOAEL: 5 x 0.1 = 0.5	21000	33000
Lead[d]	0.14	0.09	$BMDL_{01}$: 0.0006 x 0.6 = 0.00036	0.002	0.003
Formaldehyde	0.30	0.18	NOAEL: 15	52.82	82

PODsys: systemic point of departure, MOS: margin of safety, bw: body weight, NOAEL: no observed adverse effect level, BMDL: benchmark dose level

[a] 5% oral absorption

[b] 7% oral absorption (SCHER, 2015)

[c] 10% oral absorption (Chain *et al.*, 2020)

[d] 60% oral absorption (EFSA, 2010)

The MOS was more than 100 for Cr and Ni for both age groups, indicating no health concerns with regard to these HMs. However, the MOS was less than 100 for As, Cd, Pb and FA, indicating that their presence in finger paints is a cause for health concern in children with respect to non-cancer effects. The results of this risk assessment should be interpreted with caution as the outcomes of the risk assessment are also affected by many uncertainties.

1) The levels of HMs and FA used in the exposure calculations were maximum reported values, so the risks determined are likely to be overestimates of chronic risk levels. Such high concentrations of HMs and FA are unlikely to be frequently present in finger paints and the concentration data were not obtained from products available in New Zealand.
2) The dermal absorption of FA was based on a study in rats with an exposure duration of 24 or 48 hours. Dermal exposure to the FA in finger paint is likely to be much lower than this, especially if parents ensure that their children have their hands or fingers washed after using finger paint.
3) Children can also be exposed to HMs and FA from other sources, such as cosmetics, drinking water and food. However, this contribution is not assessed in this report.

For Pb and Ni, the principle of “As Low as Reasonably Achievable” should be applied so that the exposure is reduced to the lowest level practically possible. This is because no threshold concentrations have been identified for Pb (neurodevelopmental effects in children) or Ni (skin sensitisation).

The highest allowed migration limit concentration of HMs specified in the Graphic Materials Group Standard 2020 also raised health concerns in children with respect to non-cancer effects (calculations not shown). However, there were no health concerns with the limits specified in Toy Safety Directive 2009/48/EC.

5.2 OTHER HEALTH EFFECTS

FA and Cr (VI) are skin sensitisers and can cause allergic contact dermatitis resulting from dermal exposures in sensitised individuals. The threshold values for risk assessments of allergens are expressed as the 10% minimal elicitation threshold ($MET_{10\%}$), which represents the estimated dose causing a reaction in 10% of sensitised individuals. $MET_{10\%}$ is derived from exposure to an allergen dose over an area of 0.5 cm^2 for 48 hours.

FA is a known skin sensitiser and a skin/eye irritant. While the later both are reversible, skin sensitisation is induced in an individual, and may last a lifetime. In a patch test, different concentrations (0, 25, 50, 250, 500, 1,000, 5,000 and 10,000 ppm) of FA were tested (Flyvholm *et al.*, 1997). The MET or LOAEL in this study was 250 ppm (0.025%) and the NOAEL was 50 ppm (0.005%). According to CLP Regulation (EC) No 1272/2008, a mixture is classified as H317 (skin sensitisation) at an FA concentration of ≥0.2%. Therefore, a finger paint containing 0.72% FA as used in this risk assessment would be classified as a skin sensitiser and may cause an allergic reaction.

A mixture containing FA is considered an eye/skin irritant at concentrations of 5% ≤ C < 25%. Therefore, a finger paint containing 0.72% FA as used in this risk assessment may not cause skin/eye irritation.

Cr (VI) is known to cause allergic contact dermatitis resulting from dermal exposures in sensitised individuals. No information was found on the levels of Cr (VI) in finger paint. The concentrations reported in the literature are likely to be for total Cr. Various threshold values for Cr allergy have been reported in the literature, however, and $MET_{10\%}$ values for Cr (VI) from various studies were estimated to be between 0.02 and 0.9 µg/cm^2. The value of 0.9 µg/cm^2 corresponding to 3 ppm was used in the current assessment as it came from the largest study with a sample size of 54 subjects (Johansen *et al.*, 2011). Cr (III) has higher threshold levels than Cr (VI), with an estimated $MET_{10\%}$ of 0.18 µg/cm^2 (6 ppm) from the same study. Thus, the threshold limit for Cr (VI) causing an allergy lies at around 1-3 ppm. Irrespective of the isoform of Cr found in finger paints, it is likely that there is a risk of contact allergy occurring at a concentration of 9 ppm Cr, as used in the current risk assessment.

5.3 RISK CHARACTERISATION FROM OTHER STUDIES

Some of the studies reviewed performed risk characterisation calculations and compared estimates of exposure to HBGVs for some HMs. The findings of these studies are summarised below.

Rebelo *et al.* (2015) determined the content of Pb, Cd, Cr (total), Co, Ni, Mn, Cu and Zn in different paints (including finger paints) used by children in preschool establishments. The potential HM intake was estimated and compared with the TDI to assess the safety of the products. The risk assessment was performed following the RIVM guidance (Poulsen, 2014; Van Engelen *et al.*, 2015). They found that all the HMs were below the permissible migration limits set by the respective agencies in the EU and New Zealand, and the risk assessment did not raise any health risks with respect to non-cancer effects in children. It should be noted that the TDI values used in this study were substantially higher than the current TDIs established by the World Health Organization (WHO).

The Danish Environmental Protection Agency conducted a survey and health assessment of preservatives in toys (Poulsen, 2014). The risk assessment was performed according to the REACH guidance on consumer exposure and RIVM guidance on the chemical safety of toys with a focus on elements (Poulsen, 2014; Van Engelen *et al.*, 2015). For unknown reasons, finger paints were not analysed for the presence of free FA. Therefore, the highest allowed concentration of FA (0.1%) in finger paint was used in the risk assessment. The total intake

for FA was calculated as the sum of the dermal and oral absorption values, and the risk characterisation ratio (RCR) was calculated as the ratio between the total absorption and the internal derived no effect level (DNEL). It was found that the RCR was less than 1 for finger paints, leading to the conclusion that exposure to FA at 0.1% in finger paints did not pose any health risks.

6. CONCLUSIONS

Some finger paints have been reported to contain high levels of FA and HMs. This has led to product recalls from the European market. However, no information was found on similar product recalls in New Zealand. Few studies were found in the literature that have quantified FA and HM concentrations in finger paints.

In the current assessment, the total exposure to HMs and FA from finger paints was estimated as the sum of the dermal and oral exposure levels for 1 and 2-3 year old children. This estimate was made following regulatory guidance documents such as the REACH guidance on consumer exposure, the RIVM guidance on the chemical safety of toys with a focus on elements and the ConsExpo Children's Toys Fact Sheet.

The non-cancer human health risks of HMs and FA through the oral and dermal pathways were characterised by determining MOS values. The MOS was more than 100 for Cr and Ni for both age groups, indicating no health concerns. However, the MOS was less than 100 for As, Cd, Pb and FA, which indicates that their presence in finger paints is a cause of concern for childrens health with respect to non-cancer effects.

FA and Cr at the maximum concentration found in finger paints could potentially induce an allergic reaction. No threshold concentration limits have been identified for Pb (neurodevelopmental effects in children) or Ni (skin sensitisation), so the "As Low as Reasonably Achievable" principle should be applied to reduce exposure to these HMs to the lowest level practically possible.

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