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Occurrence and risk characterisation of migration of packaging chemicals in New Zealand foods

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Analyte Abbreviations

Abbreviation	Full term	Abbreviation	Full term
4-BZP	4-Benzoylbiphenyl	DIBP	Diisobutyl phthalate
4-MBP	4-Methyl-benzophenone	DIDP	Diisodecyl phthalate
BBP	Butyl benzyl phthalate	DINP	Diisononyl phthalate
BP	Benzophenone	DIPP	Diisopropyl phthalate
DBP	Dibutyl phthalate	DMP	Dimethyl phthalate
DDP	Didecyl phthalate	DMPAP	2,2-Dimethoxy-2-phenylacetophenone
DEABP	4,4'-Bis(diethylamino) benzophenone	DNOP	Di-n-octyl phthalate
DEHA	Di(2-ethylhexyl) adipate	DPP	Dipentyl phthalate
DEHP	Di(2-ethylhexyl) phthalate	EDAB	Ethyl-4-dimethyl aminobenzoate
DEP	Diethyl phthalate	EHDAB	2-Ethylhexyl-4-dimethyl aminobenzoate
DETX	2,4-Diethyl-9H-thioxanthen-9-one	HMPP	2-Hydroxy-2-methylpropiophenone
DHpP	Diheptyl phthalate	IR184	Irgacure 184 (1-hydroxycyclohexyl phenyl ketone)
DHxP	Dihexyl phthalate	ITX	2-Isopropyl-thioxanthone

1 Summary

An analytical survey has been undertaken to evaluate dietary exposure to compounds that may migrate from packaging materials into foods. Seventy four samples of various packaged and takeaway foods were analysed for phthalates and printing inks/photoinitiators.

Three phthalate moieties were detected in 15 of the sampled foods. Food types with detections included takeaway noodle dishes, and meat cuts and patties. While two results for the phthalates DEHP and DINP exceeded the European specific migration limits, dietary exposure analysis using appropriate health based guidance values established that the levels found did not pose a dietary risk.

Five printing inks/photoinitiators were detected in 11 of the sampled foods. Food types with detections included pizza and fresh meat cuts. The results for benzophenone complied with the European specific migration limit. The observed levels of the remaining four printing inks/ photoinitiators were characterised for risk using the threshold of toxicological concern. Dietary exposure assessment for all five printing inks/photoinitiators indicated that levels observed are unlikely to pose a dietary risk.

The results of the study indicate that the New Zealand public health risk of migration of phthalates and printing inks/photoinitiators from packaging into foods is negligible.

2 Introduction

Food packaging has been a staple part of food production and storage for over two centuries. Development of tinplate in the early 19th century allowed food to be preserved in quality and with microbial and chemical integrity for long periods through the canning process. In addition, modern packaging allows maintenance of the quality of food from manufacture to consumption, and for branding, labelling and protection from the external environmental. Although tin is still in use, more modern materials, such as plastics and organic fibers (both virgin and recycled), raise the possibility of chemical migration from the packaging to the food (known as packaging migration). Many forms of plastic require the presence of plasticisers, for example phthalate moieties, to provide flexibility. Other plastics may retain levels of chemicals used during their production, e.g. bisphenol A (BPA). Organic fibre packaging can also contain contaminants, either in the virgin material or if produced from recycled materials.

As packaging migration chemicals can present a human health hazard, MPI undertakes surveys of the occurrence of these chemicals in foods to obtain estimates of dietary exposure. A previous survey in 2005 evaluated the occurrence and dietary risk of BPA in selected New Zealand foods (Thomson & Grounds, 2005). This survey concluded that dietary exposures to BPA were unlikely to be of concern to adult health.

The current study was carried out to characterise the dietary risk from migration of the packaging chemicals phthalates and printing inks/photoinitiators into New Zealand foods. In addition, the project outcomes were designed to complement data from the packaging component of the Food Standards Australia New Zealand (FSANZ) 24th Australian Total Diet Survey (ATDS; FSANZ, 2016).

3 Sampling and Analysis

3.1 SAMPLING PLAN

The foods in the sampling plan were selected to complement survey work already undertaken by FSANZ, and to fill data gaps and questions raised following the ATDS (FSANZ, 2016). The primary rationale for addition of a food to the sampling plan was the detection of a packaging migration chemical in one or more samples in the ATDS.
Seventy four food/packaging combinations were selected for sampling from the 30 food groups presented in Table 1.

Table 1: Sample plan for New Zealand food packaging migration survey.

Sampled food	Samples analysed	Sampled food	Samples analysed
Bacon	2	Microwave meal	2
Bottled water	2	Milk (fresh)	2
Bread	3	Milk (UHT)	2
Butter	2	Muesli	1
Cake	2	Olives	1
Canned tomatoes	1	Other breakfast cereal	1
Canola oil spread	2	Peanut butter	2
Corn chips	2	Pizza	5
Cornflakes	2	Potato crisps	2
Crumbed chicken	2	Sausages	6
Fish	2	Takeaway Asian curry/noodles	3
Fresh meat cut	3	Takeaway chicken	3
Frozen meat patties	2	Takeaway burger/sandwich	10
Infant formula	2	Wheat biscuits	1
Infant and toddler food	2	Yoghurt/dairy dessert	4

3.2 ANALYTICAL METHODOLOGY

3.2.1 Phthalates

Analysis of samples was undertaken batch-wise with foods with similar compositions. Preparation was undertaken at room temperature but with protection from light. Test portions of 5 g ± 0.1 g were weighed out into polypropylene tubes, except for butter and dairy spread (2 g test portions); and water (50 g test portions).

All samples were fortified with an internal standard (DEHP-d_4). Further preparation prior to analysis varied depending on the food matrix. Water samples were extracted with hexane and pre-concentrated. Butter and dairy spreads were dissolved in toluene, extracted in warm acetonitrile (ACN) and fats precipitated by freezing. High moisture and high fat content foods were extracted in ethyl acetate. The extract was then pre-concentrated prior to a freeze filtration of fats using toluene and warm ACN. The ACN filtrate in both cases was then purified with gel permeation chromatography and transferred to hexane for analysis. Liquid and powdered dairy products were extracted into ACN, although the clean-up process for high fat content foods was used for high fat content dairy products.

Analysis for 14 different phthalate esters and di(2-ethylhexyl)adipate (DEHA) was undertaken using gas chromatography tandem mass spectrometry (GC-MS/MS). To monitor the extraction efficiency a quality control duplicate sample, fortified with a known amount of the target analyte, was run in each batch.

The limit of reporting (LOR) differed between food matrices and phthalate moieties. Water samples obtained LORs of 4-10 µg/kg. For other matrices the LORs were most commonly 0.1

mg/kg but ranged upto 0.5 mg/kg. The exceptions were DIDP and DINP with LORs ranging between 0.5-5 mg/kg.

3.2.2 Printing inks/photoinitiators

Test portions of 5 g of each food sample were weighed into centrifuge tubes and fortified with the surrogate standards BP-d_{10} and ITX-d_7; and the internal standard 4-fluoro-4′-hydroxybenzophenone. ACN was added and printing inks/ photo-initiators extracted with sonication and mechanical agitation. The extract was further cleaned up for dissolved fats by centrifugation and reducing the temperature to <5°C for 3 hours prior to removal of the ACN phase.

Analysis for 11 different printing inks/ photoinitiators was undertaken using liquid chromatography tandem mass spectrometry (LC-MS/MS). Method performance was monitored through the recovery of the surrogate standards in each samples. To monitor the method efficiency of each batch 30% of analysed samples were set up as quality control matrix spike samples, fortified with a known amount of the target analyte; and 10% were analysed as random duplicate samples.

The LOR was standardised at 10 µg/kg for all of the printing inks/photoinitiators. Analyte recovery at 100 µg/kg typically ranged from 71-103% in all matrices, with only DEABP recovery falling below this in meat (56%) and full fat milk (61%).

4 Results

4.1 PHTHALATES

Three phthalate moieties, including the chemically similar adipate DEHA, were detected in 15 out of the 74 sampled foods. A single sample of takeaway Asian curry/noodles contained both DEHA and DINP. The results are presented in Table 2:

Table 2: Detected results for phthalates in a survey of 74 food/packaged combinations

Sample	Packaging description	DEHA (mg/kg)	DEHP (mg/kg)	DINP (mg/kg)
Butter	Paper	0.55	ND	ND
Butter	Paper	0.58	ND	ND
Cake	Plastic wrap	ND	ND	2.2
Corn chips	Plastic/foil bag	ND	4.4	ND
Fresh meat cut	Black plastic/polystyrene tray with plastic wrap top	4.8	ND	ND
Fresh meat cut	Black plastic/polystyrene tray with plastic wrap top	5.4	ND	ND
Frozen meat patties	Black plastic tray with plastic wrap top	ND	0.39	ND
Frozen meat patties	Cardboard box	ND	ND	0.97
Pizza	Cardboard box	ND	ND	27
Sausages	Black plastic/polystyrene tray with plastic wrap top	0.58	ND	ND
Sausages	Black plastic/polystyrene tray with plastic wrap top	0.22	ND	ND
Takeaway Asian curry/noodles	Polystyrene bowl	ND	ND	4.9
Takeaway Asian curry/noodles	Opaque plastic bowl	0.35	ND	ND
Takeaway Asian curry/noodles	Clear plastic bowl	0.57	ND	1.2
Takeaway chicken	Cardboard bucket	ND	ND	1.4
Takeaway burger/sandwich	Paper bag	ND	ND	1.6

ND: Concentration <LOR

Regulatory limits for phthalate migration into foods are not described in the Australia New Zealand Food Standards Code (FSC). In their absence, the Specific Migration Limits (SML) set out in the EU under Regulation (EU) No 10/2011 are used to identify any unexpected patterns of migration:

- DEHP: 1.5mg/kg
- DEHA: 18 mg/kg
- Sum of DINP and DIDP: 9 mg/kg

A group limit has been set for DINP with DIDP as they overlap chemically with each other and are difficult to separate in mixtures.

Two of the 74 samples surveyed had concentrations of phthalates in excess of the relevant EU SML (Corn Chips in plastic/foil bag– DEHP: 4.4 mg/kg; Pizza in cardboard box – DINP: 27 mg/kg).

4.2 PRINTING INKS/PHOTOINITIATORS

Five printing inks/ photoinitiators were detected in 11 out of the 74 sampled food/packaging combinations samples. Two samples contained two different printing inks/photoinitiators and one sample contained three printing inks/photoinitiators. The results are presented in Table 3:

Table 3: Detected results for printing inks/photoinitiators in a survey of 74 food/packaging combination samples.

Sample	Packaging description	BP (µg/kg)	DETX (µg/kg)	DMPAP (µg/kg)	HMPP (µg/kg)	IR184 (µg/kg)
Canola oil spread	Plastic tub	ND	20	ND	ND	ND
Cornflakes	Plastic bag	10	ND	ND	ND	ND
Fresh meat cut	Black plastic/polystyrene tray with plastic wrap top	75	ND	ND	ND	630
Fresh meat cut	Black plastic/polystyrene tray with plastic wrap top	ND	ND	ND	ND	58
Muesli	Plastic inner, cardboard box	ND	ND	ND	18	29
Pizza	Cardboard box	17	ND	ND	ND	ND
Pizza	Cardboard box	15	ND	ND	ND	ND
Pizza	Cardboard box	11	ND	ND	ND	ND
Sausages	Black plastic/polystyrene tray with plastic wrap top	16	ND	64	ND	640
Takeaway Asian curry/noodles	Opaque plastic bowl	ND	ND	ND	21	ND
Wheat biscuits	Plastic inner, cardboard carton	13	ND	ND	ND	ND

ND: Concentration <LOR

As for the phthalates, the FSC does not describe migration limits for printing inks/ photoinitiators. The EU SML for BP (600 µg/kg) was used to identify unexpected levels of migration. The detected BP results all were below the referenced EU SML.

5 Dietary Exposure Assessment

Dietary exposure modelling was used to determine the significance of the results of the survey to the health of New Zealand consumers.

5.1 DIETARY MODEL

Model diets were constructed to calculate the dietary exposure of detected results. The model was based on the two-week simulated diets constructed for the 2016 New Zealand Total Diet

Study (NZTDS; Smith et al., 2017) for six age/gender groups, representing mean food consumption for the whole population. Foods in the current survey that were not present in the simulated diet, or recorded in a different form, were mapped to a suitable proxy and the food consumption amount from the simulated diet assigned (Table 5).

Table 5: Mapping of sampled foods in the packaging migration survey to NZTDS simulated diet foods.

Sampled food	Mapped food in NZTDS simulated diet
Cake	Cakes and Slices
Canola oil spread	Table spread
Corn chips	Potato crisps
Fresh meat cut	Beef rump
Frozen meat patties	Hamburger, takeaway
Takeaway Asian curry/noodles	Noodle dish
Takeaway chicken	Chicken takeaway
Takeaway burger/sandwich	Hamburger, takeaway

Models were run for the following age and gender groupings of the New Zealand population:

Adult Male (25+ yrs; 87 kg average bodyweight);
Adult Female (25+ yrs; 73 kg average bodyweight);
Teenage Boy (11-14 yr; 54 kg average bodyweight);
Teenage Girl (11-14 yr; 54 kg average bodyweight);
Child (5-6 yr; 23 kg average bodyweight) and
Toddler (1-3 yr; 13 kg average bodyweight).

As the prevalence of each detected phthalate or printing ink/photointiator compound across the number of sampled foods was low the dietary exposure model was scaled to a worst case scenario to screen whether the results are an exposure concern.
Typically, chronic exposure to a dietary chemical would be assessed as the mean across the diet, with non-detect results assigned to a value of either zero, half the LOR or at the LOR. A worst case scenario was adopted in this report whereby the highest detected concentration in each food was used as the expected dietary burden and the mean population exposure calculated from this. All non-detected results were treated as a zero value. The exposure estimate is acknowledged to be highly conservative as the highest detected concentration would not be consistently present in the diet over the long-term. However, this approach allows rapid assessment of the results for any dietary exposure concern. The absence of a dietary exposure concern using this worst-case scenario allows the assumption that there is not a public health risk with more realistic patterns of exposure. As this assessment was a worst-case scenario, however, the exposures generated may not be comparable with dietary exposure modelling undertaken by other countries.

5.2 PHTHALATES

5.2.1 Health based guidance values

The following health based guidance values (HGBVs) were identified for the three phthalates detected in this survey. All are based on the application of a 100-fold safety factor to the no observable adverse effect level (NOAEL) in animal studies.

- DEHA – 0.3 mg/kg bw/day (300 µg/kg bw/day; SCF, 2000)
- DEHP – 0.05 mg/kg bw/day (50 µg/kg bw/day; EFSA, 2005)
- DINP – 0.15 mg/kg bw/day (150 µg/kg bw/day; EFSA, 2005)

5.2.2 Dietary exposure calculation

As a worst-case scenario the dietary burden for the detected phthalates was estimated using the highest result detected in each commodity from any of the food/packaging combination

tested. Not detected results were treated as a concentration of zero. Estimated dietary exposures for each age group for each of the three detected phthalates were compared to the relevant HBGV, and are presented in Tables 6-8.

Table 6: Estimated dietary burden to DEHA for New Zealand age and gender groupings.

Sample	Max DEHA conc (mg/kg)	Estimated mean population exposure (µg/kg bw/day)					
		Adult Male	Adult Female	Boy	Girl	Child	Toddler
Butter	0.58	0.06	0.07	0.08	0.05	0.13	0.18
Fresh beef cut	5.4	0.75	0.59	1.40	1.10	1.41	1.66
Sausages	0.58	0.11	0.06	0.23	0.15	0.35	0.49
Takeaway Asian curry/noodles	0.57	0.37	0.24	0.10	0.07	0.17	0.00
Total exposure		1.29	0.96	1.81	1.37	2.06	2.33
Total exposure as % HBGV(300 µg/kg bw/day)		0.43	0.32	0.60	0.46	0.69	0.78

Table 7: Estimated dietary burden to DEHP for New Zealand age and gender groupings.

Sample	Max DEHP conc (mg/kg)	Estimated mean population exposure (µg/kg bw/day)					
		Adult Male	Adult Female	Boy	Girl	Child	Toddler
Corn chips	4.4	0.15	0.12	0.81	1.79	2.30	2.03
Frozen meat patties	0.39	0.08	0.04	0.15	0.27	0.24	0.36
Total exposure		0.23	0.16	0.96	1.04	1.27	1.20
Total exposure as % HBGV (50 µg/kg bw/day)		0.46	0.32	1.93	2.07	2.53	2.39

Table 8: Estimated dietary burden to DINP for New Zealand age and gender groupings.

Sample	Max DINP conc (mg/kg)	Estimated mean population exposure (µg/kg bw/day)					
		Adult Male	Adult Female	Boy	Girl	Child	Toddler
Cake	2.2	0.66	0.39	0.29	0.45	0.38	0.68
Pizza	27	4.34	4.07	5.50	6.50	10.57	10.38
Takeaway Asian curry/noodles	1.2	0.77	0.51	0.20	0.16	0.37	0.00
Takeaway chicken	1.4	0.21	0.25	0.23	0.18	0.18	0.43
Takeaway burger/sandwich	1.6	0.31	0.15	0.62	0.56	0.49	0.74
Total exposure		6.30	5.37	6.84	7.85	11.98	12.23
Total exposure as % HBGV (150 µg/kg bw/day)		4.20	3.58	4.56	5.23	7.99	8.15

5.2.3 Dietary risk characterisation

The dietary exposure estimates were undertaken using a highly conservative scenario, i.e. assuming the concentrations present in the diet will be at the maximum detected.
The assessment of worst case dietary exposure estimates of the three detected phthalate moieties present in a survey of packaged foods against relevant HBGVs indicates that there is a negligible food safety risk.

5.3 PRINTING INKS/PHOTOINITIATORS

5.3.1 Health based guidance values

The following health based guidance value was identified for one of the detected photoinitiators

- BP – 0.03 mg/kg bw/day (30 µg/kg bw/day; EFSA, 2009)

5.3.2 Threshold of toxicological concern

Health based guidance values have not been identified for the remaining four printing inks/photoinitiators, hence the threshold of toxicological concern (TTC) approach was used characterise the dietary risk (EFSA & WHO, 2016). A summary of this approach and its application to the four printing inks/photoinitiators is presented in Appendix 1.

5.3.3 Dietary exposure estimates

As a worst case scenario the dietary burden for the detected printing inks/photoinitiators was conducted using the highest result detected in each commodity. Not detected results were treated as a concentration of zero. Estimated dietary exposures for each age group for BP are presented in Table 9.

Table 9: Estimated dietary burden to BP for New Zealand age and gender groupings.

Sample	Max BP conc (µg/kg)	Estimated mean population exposure (µg/kg bw/day)					
		Adult Male	Adult Female	Boy	Girl	Child	Toddler
Cornflakes	10	0.001	0.001	0.001	0.001	0.003	0.003
Fresh beef cut	75	0.010	0.008	0.019	0.015	0.020	0.023
Pizza	17	0.003	0.003	0.003	0.004	0.007	0.007
Sausages	16	0.003	0.002	0.006	0.004	0.010	0.014
Wheat biscuits	13	0.001	0.001	0.003	0.002	0.006	0.013
Total exposure		0.018	0.014	0.032	0.026	0.046	0.059
Total exposure as % HBGV (30 µg/kg bw/day)		0.06	0.05	0.11	0.09	0.15	0.20

Dietary burdens and classification for the four printing inks/ photoinitiators detected according to the TTC approach are presented in Tables 10-13. Within the TTC methodology it is standard to use a high consumer intake to estimate the dietary exposure. This approach was not possible within this assessment, as high consumer values are not estimated in the NZTDS simulated diets. However, by using the maximum concentration of the compounds detected sufficient conservatism was retained in the assessment to ensure the outcomes remain protective to human health.

Table 10: Estimated dietary burden to DETX for New Zealand age and gender groupings, and classification under the TTC approach.

Sample	Max DETX conc (µg/kg)	Estimated mean population exposure (µg/kg bw/day)					
		Adult Male	Adult Female	Boy	Girl	Child	Toddler
Canola oil spread	20	0.0035	0.0033	0.0033	0.0026	0.0052	0.0046
TTC Class III		1.5	1.5	1.5	1.5	1.5	1.5
Decision		No Concern	No Concern	No Concern	No Concern	No Concern	No Concern
TTC carcinogenicity trigger		0.0025	0.0025	0.0025	0.0025	0.0025	0.0025
Decision		Further analysis required	Further analysis required	Further analysis required	Further analysis required	Further analysis required	Further analysis required

Table 11: Estimated dietary burden to DMPAP for New Zealand age and gender groupings, and classification under the TTC approach.

Sample	Max DMPAP conc (µg/kg)	Estimated mean population exposure (µg/kg bw/day)					
		Adult Male	Adult Female	Boy	Girl	Child	Toddler
Sausages	64	0.013	0.006	0.025	0.016	0.039	0.054
TTC Class III		1.5	1.5	1.5	1.5	1.5	1.5
Decision		No Concern	No Concern	No Concern	No Concern	No Concern	No Concern

Table 12: Estimated dietary burden to HMPP for New Zealand age and gender groupings, and classification under the TTC approach.

Sample	Max HMPP conc (µg/kg)	Estimated mean population exposure (µg/kg bw/day)					
		Adult Male	Adult Female	Boy	Girl	Child	Toddler
Muesli	18	0.01	0.004	0.004	0.004	0.003	0.006
Takeaway Asian curry/noodles	21	0.77	0.51	0.20	0.16	0.37	0.00
Total Exposure		0.78	0.51	0.20	0.16	0.37	0.01
TTC Class I		30	30	30	30	30	30
Decision		No Concern	No Concern	No Concern	No Concern	No Concern	No Concern

Table 13: Estimated dietary burden to IR184 for New Zealand age and gender groupings, and classification under the TTC approach.

Sample	IR184 (µg/kg)	Estimated mean population exposure (µg/kg bw/day)					
		Adult Male	Adult Female	Boy	Girl	Child	Toddler
Fresh beef cut	630	0.087	0.069	0.163	0.128	0.164	0.194
Muesli	29	0.004	0.002	0.002	0.002	0.001	0.002
Sausages	640	0.125	0.061	0.249	0.166	0.390	0.542
Total Exposure		0.216	0.132	0.414	0.296	0.555	0.738
TTC Class I		30	30	30	30	30	30
Decision		No Concern	No Concern	No Concern	No Concern	No Concern	No Concern

5.3.4 Dietary risk characterisation

Assessment of estimated dietary exposure to BP against the relevant HBGV indicates no health concern for any of the age groups considered.

The estimated worst case dietary exposure for DETX slightly exceeded the threshold of toxicological concern for a compound with a carcinogenicity/mutagenicity trigger (0.0025 µg/kg bw/day) requiring further detailed risk assessment.
As a heterocyclic polycyclic aromatic hydrocarbon DETX triggered the carcinogenicity/mutagenicity alerts based on its chemical structure. However, the structurally-related printing ink isopropylthioxanthone (ITX) has been reported by EFSA to not have genotoxicity potential *in-vivo* (EFSA, 2005). This reduces the weight of evidence in DETX being a carcinogenic risk.
Importantly, DETX was detected just once in a low consumption commodity. Repeated dietary exposure to DETX at the maximum concentration level found in this survey over a lifetime is highly improbable. As a result, if DETX is considered a carcinogenic hazard, the lifetime risk is likely to be below 10^{-6} (or one in a million) and therefore not a significant dietary risk.
DETX estimated dietary exposure was also analysed against the TTC class III threshold of 1.5 µg/kg bw/day, and would not be expected to be a safety concern.

Assessment of DMPAP, HMPP and IR184, against the relevant TTC classification, supports that the estimated dietary exposure is sufficiently low to conclude that the health risk is negligible.

6 Conclusion

A survey has been undertaken of a range of packaging migration chemicals in a selection of packaged New Zealand foods. Table 14 lists potential packaging migration contaminants that were not detected in any food,

Table 14: Compounds with no detected results in the survey of 74 New Zealand foods

Phthalates	Printing inks and Photoinitiators
DMP	EDAB
DEP	4-MBP
DIPP	EHDAB
DIBP	ITX
DBP	DEABP
DPP	4-BZP
DHxP	
BBP	
DHpP	
DNOP	
DIDP	
DDP	

Three phthalates and five printing inks/ photoinitiators were detected in a small number of foods. Dietary exposure to these detections was estimated through mapping to the simulated diets from the New Zealand Total Diet Study, and the health risk characterised.

One printing ink/photoinitiator DETX had an estimated dietary exposure that exceeded, albeit only slightly, the relevant TTC classification threshold based on its structure triggering carcinogenicity alerts. Further evaluation of the relevant literature indicated that a closely related printing ink has been reported to not have genotoxic potential in animal studies. In

addition, long-term consistent exposure to DETX is unlikely given detection in only one out of 74 food/packaging combination samples.

For all the other compounds detected the dietary exposure estimates showed no risk to human health. Migration of phthalates and printing inks/photoinitiators into packaged food is not a food safety concern in New Zealand.

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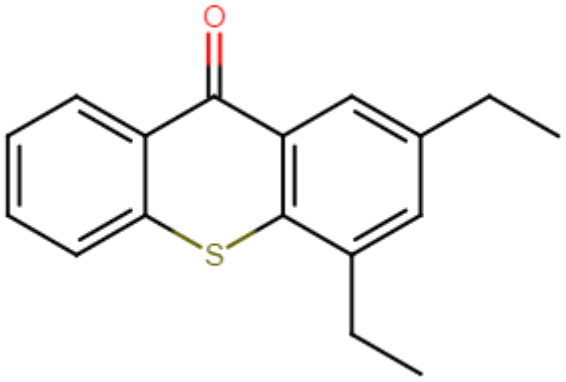
8 Appendix 1 – TTC classification

8.1 CLASSIFICATION

Classification of chemicals to the TTC was undertaken using the revised decision tree in the recently published European Food Safety Authority (EFSA) and World Health Organization review of the TTC (EFSA & WHO, 2016). For questions 1 and 4 of the decision tree, none of the four structures reviewed were in the exclusionary classes, or were organophosphates/ carbamates.

8.2 CLASSIFICATION OF DETX

Figure 1: Structure of DETX



8.2.1 Mutagenicity/carcinogenicity triggers

The structure of DETX is a heterocyclic polycyclic aromatic hydrocarbon. As a result this triggered alerts using the Benigni/Bossa rules for carcinogenicity and mutagenicity. Through use of the TTC framework a TTC of 0.0025 µg/kg bw/day was assigned to DETX. This TTC is deemed to be protective in that there is a low probability the lifetime cancer risk will exceed 1 in 10^6. Further examination of the toxicity database for DETX did not identify any genotoxicity data to evaluate the carcinogenicity and mutagenicity triggers. However, the structurally related printing ink/photointiator compound Isopropylthioxanthone (ITX) was reviewed for safety by EFSA, with genotoxicity being considered (EFSA, 2005). The conclusion for ITX was for an absence of genotoxicity potential *in-vivo*.

8.2.2 Cramer classification

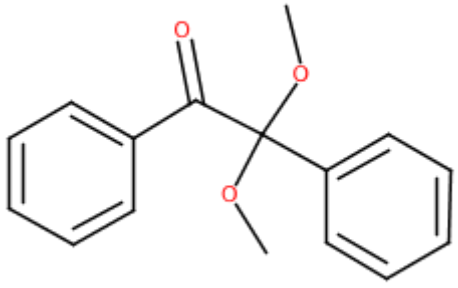
Table 16 outlines the responses to the Cramer classification scheme for DETX

Table 16: TTC classification schedule for DETX

No.	Question	Answer	Outcome
1.	Is the substance a normal endogenous constituent of the body that undergoes metabolism to CO2 and water?	No	Go to 2
2.	Does the substance contain any of the following functional groups: an aliphatic secondary amine or a salt thereof, cyano, N-nitroso, diazo (e.g. CH_2N_2), triazeno ($RN=NNH_2$) or quaternary nitrogen, except in any of the following forms: $>CN^+=R_2$, $>CN^+=H_2$ or the organic anion salts thereof?	No	Go to 3A
3A	Does the structure contain elements other than carbon, hydrogen, oxygen, nitrogen, or divalent sulphur?	No	Go to 5
5	Is it a simply branched acyclic aliphatic hydrocarbon or a common carbohydrate?	No	Go to 6A
6A	Is the substance a benzene derivative bearing substituents consisting only of (a) hydrocarbon chains or l'-hydroxy or hydroxyl ester-substituted hydrocarbon chains and (b) one or more alkoxy groups, one of which must be para to the hydrocarbon chain in (a)?	No	Go to 6B
6B	Does the compound consist of one benzene ring, with at most one heavy atom (oxygen, nitrogen or sulphur) connected to one or more of the aromatic carbon atoms?	No	Go to 7
7	Is the substance heterocyclic?	Yes	Go to 8
8	Is it a lactone or cyclic diester?	No	Go to 10
10	Is it a 3-membered heterocycle?	No	Go to 11
11	Disregarding only the heteroatoms in any one ring, does that heterocyclic ring contain or bear substituents other than simply branched hydrocarbons (including bridged chains and monocyclic aryl or alkyl structures), alkyl alcohols, aldehydes, acetals, ketones, ketals, acids, esters (including cyclic esters other than lactones), mercaptans, sulphides, thioesters, methyl ethers, hydroxy or single rings (hetero or aryl) with no substituents other than those just listed?	No	Go to 11
12	Is it heteroaromatic?	No	Go to 22
22	Is the substance a common component of food or structurally closely related to a common component of food and is the ratio between natural occurrence and the amounts added >10?	No	Go to 33
33	Does the substance bear on every major structural component at least one sodium, potassium, or calcium sulphonate or sulphamate for every 20 or fewer carbon atoms without any free primary amines except those adjacent to the sulphonate or sulphamate.	No	Class III

8.3 CLASSIFICATION OF DMPAP

Figure 2: Structure of DMPAP



8.3.1 Mutagenicity/carcinogenicity triggers

DMPAP did not trigger any alerts for carcinogenicity and mutagenicity

8.3.2 Cramer classification

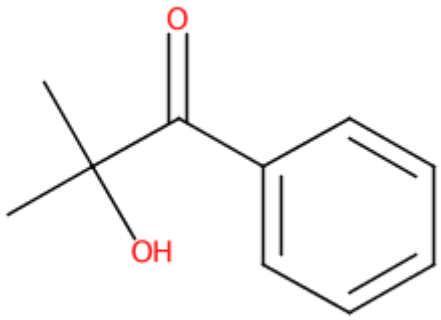
Table 17 outlines the responses to the Cramer classification scheme for DMPAP

Table 17: TTC classification schedule for DMPAP

No.	Question	Answer	Outcome
1.	Is the substance a normal endogenous constituent of the body that undergoes metabolism to CO2 and water?	No	Go to 2
2.	Does the substance contain any of the following functional groups: an aliphatic secondary amine or a salt thereof, cyano, N-nitroso, diazo (e.g. CH_2N_2), triazeno ($RN=NNH_2$) or quaternary nitrogen, except in any of the following forms: $>CN^+=R_2$, $>CN^+=H_2$ or the organic anion salts thereof?	No	Go to 3A
3A	Does the structure contain elements other than carbon, hydrogen, oxygen, nitrogen, or divalent sulphur?	No	Go to 5
5	Is it a simply branched acyclic aliphatic hydrocarbon or a common carbohydrate?	No	Go to 6A
6A	Is the substance a benzene derivative bearing substituents consisting only of (a) hydrocarbon chains or l'-hydroxy or hydroxyl ester-substituted hydrocarbon chains and (b) one or more alkoxy groups, one of which must be para to the hydrocarbon chain in (a)?	No	Go to 6B
6B	Does the compound consist of one benzene ring, with at most one heavy atom (oxygen, nitrogen or sulphur) connected to one or more of the aromatic carbon atoms?	No	Go to 7
7	Is the substance heterocyclic?	No	Go to 16
16	Is it a common terpene (D)-hydrocarbon, -alcohol –aldehyde or -carboxylic acid (not a ketone)?	No	Go to 17
17	Is the substance readily hydrolysed (H) to a common terpene (D), -alcohol, -aldehyde or - carboxylic acid?	No	Go to 19
19	Is the substance open chain?	No	Go to 23
23	Is the substance aromatic?	Yes	Go to 27
27	Does (do) the ring(s) have any substituents?	Yes	Go to 28
28	Does the structure contain more than one aromatic ring?	Yes	Go to 29
29	Is it readily hydrolysed or reduced to mononuclear residues?	No	Go to 33
33	Does the substance bear on every major structural component at least one sodium, potassium, or calcium sulphonate or sulphamate for every 20 or fewer carbon atoms without any free primary amines except those adjacent to the sulphonate or sulphamate.	No	Class III

8.4 CLASSIFICATION OF HMPP

Figure 3: Structure of HMPP



8.4.1 Mutagenicity/carcinogenicity triggers

HMPP did not trigger any alerts for carcinogenicity and mutagenicity

8.4.2 Cramer classification

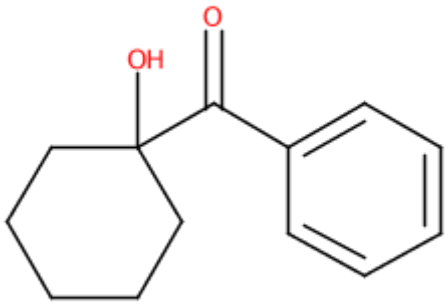
Table 18 outlines the responses to the Cramer classification scheme for HMPP

Table 18: TTC classification schedule for HMPP

No.	Question	Answer	Outcome
1.	Is the substance a normal endogenous constituent of the body that undergoes metabolism to CO2 and water?	No	Go to 2
2.	Does the substance contain any of the following functional groups: an aliphatic secondary amine or a salt thereof, cyano, N-nitroso, diazo (e.g. CH_2N_2), triazeno ($RN=NNH_2$) or quaternary nitrogen, except in any of the following forms: $>CN^+=R_2$, $>CN^+=H_2$ or the organic anion salts thereof?	No	Go to 3A
3A	Does the structure contain elements other than carbon, hydrogen, oxygen, nitrogen, or divalent sulphur?	No	Go to 5
5	Is it a simply branched acyclic aliphatic hydrocarbon or a common carbohydrate?	No	Go to 6A
6A	Is the substance a benzene derivative bearing substituents consisting only of (a) hydrocarbon chains or l'-hydroxy or hydroxyl ester-substituted hydrocarbon chains and (b) one or more alkoxy groups, one of which must be para to the hydrocarbon chain in (a)?	No	Go to 6B
6B	Does the compound consist of one benzene ring, with at most one heavy atom (oxygen, nitrogen or sulphur) connected to one or more of the aromatic carbon atoms?	No	Go to 7
7	Is the substance heterocyclic?	No	Go to 16
16	Is it a common terpene (D)-hydrocarbon, -alcohol –aldehyde or -carboxylic acid (not a ketone)?	No	Go to 17
17	Is the substance readily hydrolysed (H) to a common terpene (D), -alcohol, -aldehyde or - carboxylic acid?	No	Go to 19
19	Is the substance open chain?	No	Go to 23
23	Is the substance aromatic?	Yes	Go to 27
27	Does (do) the ring(s) have any substituents?	Yes	Go to 28
28	Does the structure contain more than one aromatic ring?	No	Go to 30
30	Disregarding ring hydroxy or methoxy does the ring bear substituents other than 1-5 -carbon aliphatic groups, either hydrocarbon or containing alcohol, ketone, aldehyde, carboxyl or simple esters that may be hydrolysed to ring substituents of five or less carbons?	No	Go to 18
18	Is the substance one of the following? a vicinal diketone; or a ketone or ketal of a ketone attached to a terminal vinyl group or, a secondary alcohol, ester or thioester of a secondary alcohol attached to a terminal vinyl group or, allyl alcohol or its acetal ketal or ester derivative or, allyl mercaptan, an allyl sulphide, an allyl thioester or allyl amine or, acrolein, a methacrolein or their acetals or, acrylic or methacrylic acid or, an acetylenic compound or, an acyclic aliphatic ketone, ketal or ketoalcohol with no other functional groups and with four or more carbons on either side of the keto group or, a substance in which the functional groups are all sterically hindered.	No	Class I

8.5 CLASSIFICATION OF IR184

Figure 4: Structure of IR184



8.5.1 Mutagenicity/carcinogenicity triggers

IR184 did not trigger any alerts for carcinogenicity and mutagenicity

8.5.2 Cramer classification

Table 19 outlines the responses to the Cramer classification scheme for IR184

Table 19: TTC classification schedule for IR184

No.	Question	Answer	Outcome
1.	Is the substance a normal endogenous constituent of the body that undergoes metabolism to CO2 and water?	No	Go to 2
2.	Does the substance contain any of the following functional groups: an aliphatic secondary amine or a salt thereof, cyano,N-nitroso, diazo (e.g. CH_2N_2), triazeno ($RN=NNH_2$) or quaternary nitrogen, except in any of the following forms: $>CN^+=R_2$, $>CN^+=H_2$ or the organic anion salts thereof?	No	Go to 3A
3A	Does the structure contain elements other than carbon, hydrogen, oxygen, nitrogen, or divalent sulphur?	No	Go to 5
5	Is it a simply branched acyclic aliphatic hydrocarbon or a common carbohydrate?	No	Go to 6A
6A	Is the substance a benzene derivative bearing substituents consisting only of (a) hydrocarbon chains or l'-hydroxy or hydroxyl ester-substituted hydrocarbon chains and (b) one or more alkoxy groups, one of which must be para to the hydrocarbon chain in (a)?	No	Go to 6B
6B	Does the compound consist of one benzene ring, with at most one heavy atom (oxygen, nitrogen or sulphur) connected to one or more of the aromatic carbon atoms?	No	Go to 7
7	Is the substance heterocyclic?	No	Go to 16
16	Is it a common terpene (D)-hydrocarbon, -alcohol –aldehyde or -carboxylic acid (not a ketone)?	No	Go to 17
17	Is the substance readily hydrolysed (H) to a common terpene (D), -alcohol, -aldehyde or - carboxylic acid?	No	Go to 19
19	Is the substance open chain?	No	Go to 23
23	Is the substance aromatic?	Yes	Go to 27
27	Does (do) the ring(s) have any substituents?	Yes	Go to 28
28	Does the structure contain more than one aromatic ring?	No	Go to 30
30	Disregarding ring hydroxy or methoxy does the ring bear substituents other than 1-5 -carbon aliphatic groups, either hydrocarbon or containing alcohol, ketone, aldehyde, carboxyl or simple esters that may be hydrolysed to ring substituents of five or less carbons?	No	Go to 18
18	Is the substance one of the following? a vicinal diketone; or a ketone or ketal of a ketone attached to a terminal vinyl group or, a secondary alcohol, ester or thioester of a secondary alcohol attached to a terminal vinyl group or, allyl alcohol or its acetal ketal or ester derivative or, allyl mercaptan, an allyl sulphide, an allyl thioester or allyl amine or, acrolein, a methacrolein or their acetals or, acrylic or methacrylic acid or, an acetylenic compound or, an acyclic aliphatic ketone, ketal or ketoalcohol with no other functional groups and with four or more carbons on either side of the keto group or, a substance in which the functional groups are all sterically hindered.	No	Class I