

PACKAGING – MIGRATION AND HARMFUL ELEMENT COMPLIANCES



By : Mr. Dilip Singh
National Manager
SGS India Pvt. Ltd.

WHEN YOU NEED TO BE SURE



CONCEPT OF MIGRATION TESTING

- How do you know if the food packaging you wrap your Food in is safe?
- Food contact materials must not transfer their components into food in quantities that could:
 - endanger human health,
 - change food composition in an unacceptable way, or
 - deteriorate the organoleptic characteristics of food
- Overall migration limit (OML)
- Specific migration limit (SML)



TYPES OF MIGRATION AND OTHER TESTS



- Overall migration
 - To see how many amount of residual from packaging material migrated into foodstuff
 - Limit shall not exceed 10 mg/dm² or 60 mg/kg
- Specific migration
 - To see how many specific chemical substances from packaging material migrated into foodstuff
 - Requirements of chemical are listed in Standards
- Monomer or additive content Limits
 - BPA content (Not to be used for the manufacture of Polycarbonate infant feeding bottles)
 - Vinyl Chloride Monomer (PVC Material)
 -

OVERALL MIGRATION – LIST OF FOOD SIMULANTS (EU)

List of food simulants (General assignment)

Food Type	ANNEX III Regulation (EU) 10/2011
Aqueous	10% Ethanol [A]
Acidic	3% Acetic acid [B]
Alcoholic	20% Ethanol [C]
	50% Ethanol [D1]
Fatty	Vegetable Oil [D2]
Dry	Poly-(2,6-diphenyl-p-phenylene oxide) particle size 60-80 mesh, pore size 200 nm (Tenax) [E]
Milk	Covered by 50% Ethanol [D1] as “oil-in-water emulsion”

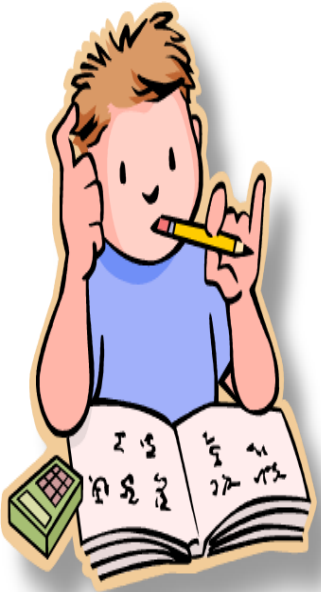


OVERALL MIGRATION -LIST OF FOOD SIMULANTS (IS)



List of food simulants (General assignment)	
Food Type	Table 1 IS 9845
Aqueous	Distilled Water [A]
Acidic	3% Acetic acid [B]
Alcoholic	10% Ethanol [C1]
	50% Ethanol [C2]
Fatty	N-heptane [D]
Dry	No end test

OVERALL MIGRATION – SELECTION OF FOOD SIMULANTS



Food simulant assignment for testing overall migration (Annex III Regulation (EU) No. 10/2011)

Food Type Considered	Food Simulants
All food types	10% Ethanol (or water) 3 % acetic acid vegetable oil
All food types except acidic food	10% Ethanol (or water) vegetable oil
Aqueous, acidic and alcoholic foods and milk products	3% acetic acid 50% ethanol
Aqueous and up to 20% alcoholic foods	20% Ethanol
Aqueous and acidic foods and up to 20% alcoholic foods	3% Acetic acid 20% ethanol

OVERALL MIGRATION – SELECTION OF TEST CONDITIONS



Standardized overall migration conditions		
Test No.	Conditions (Temperature and Time)	Intended food contact conditions
OM1	20 °C for 10 d	Food contact at frozen and refrigerator conditions
OM2	40 °C for 10 d	Long term storage at room temperature or below including heating up to 70°C for 2 h or heating up to 100 °C for 15 min
OM3	70 °C for 2 h	Heating up to 70°C for 2 h or up to 100 °C for 15 min (not followed by long term room or refrigerated temperature storage)
OM4	100 °C for 1 h	All food simulants at temperatures up to 100 °C
OM5	2h at 100 °C or reflux for 1 h or 121 °C for 1 h	Applications up to 121 °C
OM6	100 °C for 4 h or reflux	Food contact conditions with 10% or 20% Ethanol or 3% Acetic acid above 40 °C
OM7	175 °C for 2 h	High temp. applications with fatty food exceeding conditions in OM5 (OM8 and OM9) if technically not feasible

OVERALL MIGRATION – SELECTION OF TEST CONDITIONS

Standardized overall migration conditions

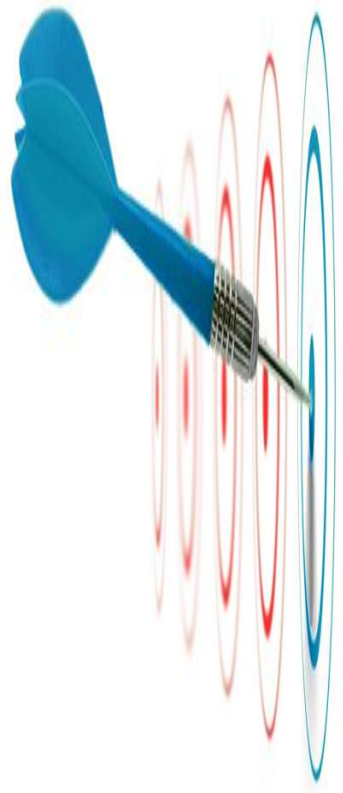
Substitute test for OM 7 using vegetable oil (175 °C for 2 h), OM8 or OM 9

Test No.	Condition (Temperature and Time)	Intended food contact conditions	Covers
OM8	<ul style="list-style-type: none"> • Tenax at 175 °C for 2 h, and • Vegetable oil at 100 °C for 2 h 	High temp applications only	OM1, OM3-OM6
OM9	<ul style="list-style-type: none"> • Tenax at 175 °C for 2 h, and • Vegetable oil at 40 °C for 10 d 	High temp applications including long term storage	OM1 – OM6

Both conditions for OM8 or OM9 must be performed




SPECIFIC MIGRATION LIMIT (SML)



Heavy Metal	EU (No) 2017/752 Migration Limit (mg/kg)
Barium	1
Cobalt	0.05
Copper	5
Iron	48
Lithium	0.6
Manganese	0.6
Zinc	5
Aluminum	1
Nickel	0.02
Effective date	May 19, 2019



Phthalate	Migration limit (mg/kg)
BBP	30
DEHP	1.5
DBP	0.3
DINP	9
DIDP	9
Diallyl	Not detected



Migration	High risk materials	Limit
Aromatic amines	Nylon, Polyurethane	Not detected
Bisphenol A	PC, PVC	0.05 mg/kg
Melamine	Melamine	2.5 mg/kg
Formaldehyde	Melamine, POM	15 mg/kg
Caprolactam	Nylon-6	15 mg/kg
Hexamethylene diamine	Nylon-66, Nylon-612	2.4 mg/kg
Acrylonitrile	Acrylonitrile-containing polymers, e.g. ABS, SAN	Not detected
1-Octene	PP, PE	15 mg/kg
1-Hexene	PP, PE	3 mg/kg
Ethylene Glycol, Diethylene Glycol	PET	Sum 30 mg/kg

MONOMER AND SUBSTANCE LIMITS



- PAH content
- Total content of vinyl chloride monomer (for PVC)
- Phthalate content
- BPA content
- Peroxide residues , VOM etc.
- Heavy metals in packaging as per 94/62/EC or CONEG
- Screening for 174 SVHCs as per updated candidate list of REACH
- PCP, PCB content
- FDA GRAS (material composition) for stainless steel
- Lead contamination in silver plated hollow ware as per CPG Sec. 545.500
- Sensory test
- Lead and Cadmium compounds
- Transfer of antimicrobial agents
- Manufacturing residues in PET
- Residual styrene monomer in Polystyrene
- MOSH/MOAH



Test requirements on printing inks for food packaging

- Heavy Metals
- Plasticizers
- Other compounds (e.g. asbestos , flame retardants , dioxins , nitrosamines , furans , PCP, PCBs, VCM etc.)
-

Requirements on color pigments / master batches for plastics

- Heavy Metals
- Primary aromatic amines
- PCBs
- Sulphonated amines
- Carcinogenic amines
-

SGS

Thank You !!!

WWW.SGS.COM

WWW.SGSGROUP.IN