



April 14, 2021

To: Gold Medal

Re: **Thermoformed** "Goods"

Dear Customer,

Detroit Forming, Inc. ("DFI") submits this Statement in response to your request concerning the above Goods and compliance with certain legal standards or requirements as explained below. All statements are made in good faith, to the best of DFI's knowledge, as of the date above, and are subject to the disclaimer at the end of this Statement.

FDA Status

The materials selected to formulate the Goods are listed in one or more of the following sections of Title 21, Code of Federal Regulations:

Conditions of Use:

The Goods may be used in contact with all types of food including articles used for packing or holding food for Conditions of Use A-H as shown in Tables 1 and 2 of 21 C.F.R. § 176.170(c). The materials are subject to the extraction limits shown in the regulation.

The section above list raw materials approved by the U.S. Food and Drug Administration (FDA) for use in food contact applications, such as packaging, and are subject to good manufacturing practices and any limitations contained in applicable United States regulations. This statement refers to the extraction limitations only, not to the Good's physical utility. It is the responsibility of the Customer to determine if the Goods are suitable for their intended use.

Current Good Manufacturing Practices (cGMP)

Detroit Forming is committed to complying with applicable regulations governing current Good Manufacturing Practices ("cGMP"). Internal audits are conducted to assure compliance with cGMP procedures. We work diligently with our suppliers to also ensure their compliance with cGMP.

Therefore, the Goods are hereby guaranteed, as of the date of such shipment or delivery, to be not adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act.

HACCP (Hazard Analysis and Critical Control Points)

DFI has conducted a Hazard Analysis to determine the possible biological, chemical, or physical hazards that may contaminate the thermoformed plastic food containers manufactured for our customers. Four control points have been determined where possible hazards may have the potential to contaminate raw materials, processing, storage, or distribution of our containers within the production and distribution operations at our five locations.

It is the opinion of the HACCP Coordinator and our HACCP Team that the pre-requisite programs in place and maintained by DFI provide sufficient controls to protect the product from contamination and prohibit the distribution of unsafe food containers to our customers or end users.

The Plant Manager at each of our facilities is responsible for maintaining the pre-requisite programs and will ensure that the necessary monitoring and record keeping is performed in accordance with the DFI guidelines. Records of the site's pre-requisite programs will be maintained in each of our facilities.

An annual assessment and periodic audits will be conducted to verify compliance and effectiveness of the pre-requisite programs. Observations and corrective actions necessary to maintain a hazard free manufacturing operation will be filed and used for subsequent reviews.

The Management Team consists of the V.P. Operations, Manufacturing Directors, Plant Managers, Customer Service, Logistics, Warehouse Managers and QA Personnel. At each location, the Plant Manager will be the HACCP Coordinator.

GFSI (Global Food Safety Initiative)

DFI is subject to annual GFSI certification audits conduct by **SAI Global** for **IFS PACsecure**.

Undesirable Substances

Based on representations of the suppliers of the materials from which the Goods are produced, the Goods are, on the date of shipment or delivery, not manufactured to contain or have intentionally added substances.

Detroit Forming does not analyze for the substance(s) as it (they) are not expected to be present.

- **Azo dyes** - azo compounds as defined in (EU Directive 2002/61/EC nor are expected to release carcinogenic aromatic amines
- **Benzophenone** (CAS RN: 119-61-9)
- **BPA**- Bisphenol A (BPA) and/or Thalates in food contact materials.
- **Dimethyl Fumarate** – dimethyl fumarate as defined in EU Commission Directive 2009/251/EC. In accordance with EU Commission Directive 2009/251/EC, a product or part of a product containing more than 0.1 mg/kg of Dimethyl Fumarate is prohibited from being placed or made available on the EU market.
- **GMOs** - (genetically modified organisms), nor are the Goods considered genetically modified according to EU directive 90/219/EC and as amended in directive 2001/18/EC
- **Latex**
- **Melamine** – DFI does not intentionally use any melamine in the formulation or manufacturing processes of the Goods and does not use any components in the Goods which are at-risk for melamine contamination as listed in FDA guidance.
- **Nano substances** – nano substances generally described as <100 nm in one or more dimension.
- **Ozone depleting substances** – ozone depleting substances as defined as Class I or Class II substances as defined under 40 C.F.R., part 82 and EU Regulation 2037/2000/EC. **Organotin compounds** – organotin compounds such as **TBT, TPhT, DOT, DBT** banned in products >1000ppm (greater than 0.1% by weight) according to EU Commission Decision 2009/425/EC.
- **PFOA/PFOS/PFAS** - perfluorooctane sulfonates (PFOS) or perfluorooctanoic acid (PFOA) or perfluoroalkyl/polyfluoroalkyl substances(PFAS) as defined in European Union (EU) Council Directive 2006/122/EC: PFOS and PFOA.
- **Phenols** - Phenols including alkyl-, octyl- phenols or alkylphenol ethoxylates.
- **Phthalates** - Phthalates including di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP), di-isononyl phthalate (DINP).

- **Polystyrene** - DFI uses FDA approved polystyrene to manufacture our containers. Polystyrene as documented in Title 21 of CFR 177.1330 and CFR 177.1640 meets the federal guideline for chemical migration when used for its intended purpose. Therefore, a Chemical Migration Study is not necessary
- **Preservatives – e.g. BHT, BHA** Preservatives are not added as a part of our formulation. The Materials used in the manufacture of the Goods, however, may be formulated with a thermal stabilizer. The thermal stabilizer is considered a technical agent and not intended to impart any added functionality to the Goods.
- **Synthetic Fungicides, Preservatives, Fumigants**

Heavy Metal Content (CONEG)

Based on representations of the suppliers of the Materials from which the Goods are produced, the Goods are, on the date of shipment or delivery, in compliance with the relevant heavy metals requirements, and all current applicable amendments, for the CONEG (Coalition of Northeastern Governors) Reduction of Toxics in Packaging Acts, California Toxics in Packaging Prevention (TIPP) Act, and European Union Council Directive 94/62/EC, Article 11.

DFI certifies that the regulated metals--lead, mercury, cadmium and hexavalent chromium (Chrome Six)--were not intentionally added to the Goods during the manufacturing process and that the sum of the incidental concentration levels of lead, mercury, cadmium and hexavalent chrome present in any package or package component does not exceed 100 parts per million by weight.

California Proposition 65 chemical content

Based on representations of the suppliers of the materials from which the Goods are produced, the Goods do not, on the date of shipment, contain any substances (“Listed Substances”) that are: (i) intentionally added during the manufacturing process or (ii) known or expected to be present at an exposure level requiring a warning under the current provisions of California Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986 (“Proposition 65”).

This representation is based solely on a compilation of the most recently received information from our suppliers. Proposition 65 states “no significant risk levels” for carcinogens (“NSRL”) and “maximum allowable dose levels” for chemicals that may cause reproductive toxicity (“MADL”) in terms of theoretical exposure levels of micrograms per day (“µg/day”), but manufacturers and suppliers refer to the presence of Listed Substances in terms of actual concentration levels of parts per million (“ppm”). California has not published any guidelines or tables that could be broadly applied to enable manufacturers or others to readily convert actual concentration levels to theoretical exposure levels and therefore statements to the effect that Listed Substances are present at levels that do not require warnings depend on certain assumptions about consumers' exposure and cannot be precise. We do not conduct any independent tests for Listed Substances and disclaim any responsibility to do so.

Food Allergens

Based on representations of the suppliers of the resins and additives from which the Goods are produced, the Goods are, on the date of shipment or delivery, not manufactured to contain food allergens as indicated in the United States Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) or European Union Regulation (EU) No 1169/2011, Annex II regarding the indication of the ingredients in foodstuffs.

In addition, the manufacturing areas owned and operated by DFI-Detroit Forming Inc. do not use or have present, to the best of our knowledge, any of the eleven following allergens:

- Peanuts (or derivatives)
- Tree nuts (or derivatives)
- Sesame (or derivatives)
- Milk (or derivatives)
- Eggs (or derivatives)
- Fish (or derivatives)
- Shellfish (or derivatives)
- Soy (or derivatives)
- Wheat (or derivatives)
- Sulphites (or derivatives) Sulphites are used to bleach food starches (e.g., potato) and are also used in the production of some food packaging materials (e.g., cellophane). potassium bisulphite, potassium metabisulphite, sodium bisulphite, sodium dithionite, sodium metabisulphite, sodium sulphite, sulphur dioxide and sulphurous acid.
- Mustard (or derivatives)

We do not restrict or monitor our employee's consumption of these food items; however, there are safeguards in place to prevent cross contamination such as:

- Eating is restricted to lunchroom and break areas
- Hands must be washed before returning to production line after food consumption

As a result, Goods comprising each shipment or delivery made by DFI are in compliance with U.S. Food, Drug and Cosmetic Act, the U.S. Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) and European Union Regulation (EU) No 1169/2011, Annex II.

Bioterrorism Act/Food Safety Defense

The Bioterrorism Act of 2002 has many components to the legislation.

DFI is not a food producer or food processor, and therefore is not required to be registered with the FDA under the ACT. DFI does take the necessary precautions to secure our facilities and to protect our products from intentional adulteration.

DFI believes that the overall site security reinforced with employee awareness training is key to thwarting an intentional act from contaminating the Goods. These include physical controls, key and code policies, IT security, inbound and outbound transportation procedures, visitor/ contractor policies, and hiring practices that support the necessary protections to make the supply chain safe for our customers.

Canadian Food Inspection Agency (CFIA) Approvals

The Goods are accepted construction materials, packaging materials and non-food chemical Goods listed on the Canadian Food Inspection Agency's website (www.inspection.gc.ca). The Goods are manufactured from materials that are in compliance with Health Protection Branch (HPB) and are safe to use in articles intended for food contact.

Health Canada / Canadian Food Inspection Agency (CFIA) Approvals

Although the Goods have not been submitted to the Canadian Food Inspection Agency / Health Canada for approval and inclusion on the Canadian Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products, the suppliers of the materials indicate that they have received Letters of No Objection from

Health Canada indicating that they have been reviewed and are acceptable for use in food packaging applications; or they have received letters from Health Canada indicating that their material is approved "In Principle"; or their material is made from materials that are in compliance with the Health Canada's Health Products and Food Branch, and are included in the Canadian Food Inspection Agency's (CFIA) "Reference Listings of Accepted Packaging Materials and Non-Food Chemical Products."

Declaration of Regulatory Compliance EU/US

The composition of the Goods manufactured and identified as

DFI Europe OPS Grade(s) E, F and G

DFI Detroit Forming, Inc. United States of America

Is/are manufactured for and supplied by

DFI Europe s.r.o., Ceskoslovenske Armady 1053, 253 01 Hostivice, Czech Republic.

DFI Detroit Forming, Inc., 19100 W 8 Mile Road, Southfield, MI 48075

The finished product(s) bi-oriented polystyrene, commonly referred to as OPS or BOPS comply with the relevant aspects of the following food contact regulations on materials and articles:

EU (European Union) Legislation:

- **Regulation (EC) No 1935/2004 of the European Parliament and of the Council** on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.
- **Commission regulation (EC) No 2023/2006** on good manufacturing practices for materials and articles intended to come into contact with food.
- **Commission regulation (EU) No 10/2011, Commission Regulation (EU) No 1282/2011, No 1183/2012, No. 202/2014, No. 865/2014, No. 174/2015, No. 1416/2016 and Commission Regulation (EU) 752/2017** amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food. The supporting documents based on the basic rules for overall and specific migration testing according to the Annex to Directive 82/711/EEC, and in conformity to Article 22 – Transition provisions, Chapter VI – Final provisions. The original substances, used in the manufacturing of the mentioned above products, are listed in the Union list of authorized monomers, other starting substances, additives and polymer production aides with the following restrictions:

Specific migration limit (SML) for monomers, additives and other starting substances are:

Zinc Stearate	CAS reg. No. 557-05-1	Specific migration limit = 25 mg/kg
1-3 Butadiene	CAS reg. No. 000106-99-0	(Ref. No. 13630, butadiene) Specific migration limit = ND (not detectable)
Acrylic acid (2,4-di-tert-pentyl-6-(1-(3,5-di-tert-pentyl-2-hydroxyphenyl)ethyl)phenylester)	CAS reg. No. 123968-25-2	Specific migration limit = 5 mg/kg

Overall migration limit (OML) for monomers, additives and other starting substances is 10mg/dm² or 60 mg/kg.

Dual Use (substances listed as food additives as well as food contact additives)

We have re-confirmed with our raw material suppliers that they did review the substances which are used as additives in the manufacture of the raw materials which are used to produce the above mentioned products regarding dual use additives, meaning additives that are approved for food contact materials according to Regulation 10/2011/EC and as direct food additives according to Regulation 1333/2008/EC and 1334/2008/EC and they found no substances which can be classified as dual use substances.

The above mentioned Goods when colored white contain dual use substance (Titanium dioxide) within specific migration limits.

- **Directive 2002/16/EC** and its latest modification **Regulation EC 1895/2005** on the restriction of use of certain epoxy derivatives in material and articles intended to come into contact with food.
- **Directive 94/62/EC** and its latest modification **Directive 2004/12/EC** “on packaging and packaging waste”.

National legislation:

- **Italy:** *D.M. 21/03/1973* and following amendments including *D.M. 322/1999* “concernente la disciplina igienica degli imballaggi, recipienti, utensili destinati a venire a contatto con le sostanze alimentari o con sostanze d’uso personale” and *D.M. 227/2006*. D.P.R. n.777 23/08/1982.
- **France:** *Décret n°98/638* “transposition de la Directive 94/62/CE emballages et déchets d’emballage” and *Décret Ministériel n° 73-138 du 12/02/73* contained in the brochure *L. 1227* “Matériaux au contact des denrées alimentaires, produits de nettoyage de ces matériaux” (dernière édition : 15/07/2002) ; *Arrêté du 09/08/2005* “relatif aux matériaux et objets en matière plastique mis ou destinés à être mis au contact avec les denrées, produits et boissons alimentaires”.
- **Germany:** *Bedarfsgegenstandeverordnung* dated 23/12/1997 and following amendments; *BfR IX* dated 01/06/1994 and following amendments “colorant for Plastics and other Polymers used in commodities”; *BfR V* dated 01/03/2001 and following amendments “polystyrene produced exclusively from the polymerisation of styrene”; *BfR VI* dated 01/04/2004 and following amendments “Styrene copolymers and graft polymers, and mixtures of polystyrene with other polymers”; *BgVV Empfehlung V: “Polystyrol”* Stand 01/02/2005.
- **Holland:** *Verpakkingen en Gebruikaartikelen Besluit (Warenwet) 21/08/1991* and its latest amendment Dec. 2005.
- **Belgium:** *Arrêté Royal 03/07/2005* “Matériaux et objets destinés à entrer en contact avec les denrées alimentaires” and its latest amendment dated 05/07/2006.
- **UK:** “Material and articles in Contact with food Regulations”: *Statutory Instruments 1987/1523*, as amended by *S.I. 1994/979*; *Statutory Rules 1998/1376* as amended by *S.I. 2002/3008* and *S.I. 2006/1401*, *Statutory Instruments 2001/1263* as amended by *S.I. 2003/302*; *Statutory Instrument 2002 N° 2364* “The plastic materials and articles in contact with food, Regulations 2002” and following amendments.
- **Spain:** *Real Decreto 118/2003* dated 31/01/2003 and its latest amendment *R.D. 1262/2005*; *Orden SCO/983/2003*.
- **Switzerland:** *SR 817.041.1* “Ordinanza del dipartimento federale dell’interno sui materiali e oggetti in materia plastica” dated 26/06/1995 and its following amendments
- **USA:** *Code of Federal Regulation* - Title 21, § 177.1640 “Polystyrene and rubber-modified polystyrene”.

Migration testing for food contact applications

April 14, 2021

Concerning specific migration limits, based on migration calculations, the SMLs should not be exceeded on the use of the above-mentioned material in food contact applications. This refers to standard conditions of use (10 days, 40°C, 1 kg of food in contact with 6dm² of packaging, 250 µm thickness). We are not aware of any restriction on the use with specific types of food.

Finished products regulatory requirement

End-use article manufacturers using the above product for the fabrication of finished products (materials/articles) intended to come into contact with food are responsible for and must comply with the above-mentioned restrictions/limitations (OML, SML, etc.). They are also required to comply with the general regulatory requirements (Regulation (EC) No. 1935/2004, Art. 3) that these materials/articles do not bring about an unacceptable change in the composition of the foodstuffs or deterioration in the organoleptic characteristics thereof.

Effective Date

This Statement: (i) is effective only as of the above date; (ii) revokes any prior statements or representations by us with respect to the subject matter; (iii) may be withdrawn at any time.

This Statement is not intended to modify any existing supply agreement or other agreement between the parties or to relieve Buyer from its obligations to: (i) comply with applicable laws; (ii) provide accurate data for decorating and labeling of Goods; and (iii) use the Goods in a manner consistent with those data. DFI disclaims any responsibility for and shall not be liable for: (i) any modification of the Goods after shipment; (ii) Buyer's use or storage that may result in degradation of the Goods or migration of other chemicals into the Goods; (iii) any non-conforming materials or any modification of materials by a Supplier; (iv) any addition to or amendment of any applicable European, U.S., state or local laws or regulations relating to the materials, or the Goods; or (v) actions required by Buyer to comply with applicable European, U.S., state, and local laws relating to the materials or the Goods. Buyer is responsible for determining and applying the law and regulations that may be applicable to the intended use of the Goods, whether alone or with any other substance, and determining if the Goods are suitable for their intended use. The chemical compositions for the materials and the Goods may be proprietary formulations and, if so, are confidential.

Disclaimer

ASIDE FROM THE STATEMENTS ABOVE, NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY PURPOSE, OR ANY OTHER WARRANTY OR GUARANTEE IS MADE OR IMPLIED REGARDING THE GOODS OR THE REPRESENTATIONS OF DFI'S SUPPLIERS, THE RESULTS TO BE OBTAINED FROM THE USE OF THE GOODS, THE SAFETY OF THE GOODS, OR THE HAZARDS CONNECTED WITH THE USE OF THE GOODS. ALL SUCH WARRANTIES ARE EXCLUDED.

Should you need additional information concerning the composition of the Goods, please do not hesitate to contact us.

Thank you for your business.

Sincerely,

Catherine Rodney
President