# DECLARATION OF COMPLIANCE

Product reference: **IST-104**

as supplied by: IST Scientific LLP, Unit 34-36, Carlton Park Industrial Estate, Main Road, Saxmundham IP17 2NL, UK

This product is composed of the following components:

**table 1 – product composition (from the external layer to the internal layer).**

| | |
|---|---|
| 12 µ | oriented polyester film, printed |
| ± 4 µ | adhesive (polyurethane based) |
| 8 µ | aluminium foil |
| ± 4 µ | adhesive (polyurethane based) |
| 50 µ | peelable polyethylene film |

The exact nature of the components used IST Scientific LLP proprietary information. Details of the formulation could be supplied to an independent third party under secrecy agreement.

## 1. Compliance with food contact legislation.

This product complies with Regulation (EC) No 1935/2004. In particular, it is manufactured under good manufacturing practices, from components and ingredients which are declared suitable for food contact use, and is therefore considered to comply with the general safety requirements (Art. 3). We also comply with Art. 11(5), the provisions on labelling (Art. 15), declaration of compliance (Art. 16) and traceability (Art. 17). See below for details on the conditions of use.

Our good manufacturing practices meet the requirements of Regulation (EC) No 2023/2006 and follow relevant sections of the "Code for Good Manufacturing Practices for Flexible and Fibre-Based Packaging for Food" issued by Flexible Packaging Europe (http://www.flexpack-europe.org/).

The following table lists the regulatory status of the components used in manufacturing our product:

**table 2 – regulatory status of product components.**

| **Component** | **Legal Reference** | **Status** (**) |
|---|---|---|
| plastics | Regulation (EU) No 10/2011 (*) | monomers & additives listed; see below for further compliance aspects. |
| plastics | FDA 21 CFR section 177.1520 and 177.1630 | compositional compliance. |
| recycled plastics | Regulation (EC) No 2022/1616 | plastics in scope of Reg. 2022/1616 are not used. |
| active & intelligent | Regulation (EC) No 450/2009 | A&I are not used. |
| vinyl chloride monomer | Directive 78/142/EEC | VCM is not used. |
| bisphenol A | Regulation (EU) 2018/213 | BPA is not used. |
| epoxy derivatives | Regulation (EC) No 1895/2005 | epoxy is not used. |
| nanomaterials | Recommendation 2011/696/EU | nanomaterials used are: ink pigments and silica (which are non-migratory). |
| biocides | Regulation (EU) No. 528/2012 | biocides are not used. |
| PFAS | Connecticut (SB837)<br>Minnesota (Statute 325F.075)<br>Rhode Island (S2044/H7438)<br>Vermont (S20/2021) | PFAS are used, therefore this product does not comply. |

| | | |
|---|---|---|
| adhesives | Regulation (EU) No 10/2011 (*)<br>BfR XXVIII<br>FDA 21 CFR 175.105 | compositional compliance with at least one of these legal references. |
| printing inks | n.a. | comply with EuPIA exclusion policy.<br>comply with LFGB §§ 30-31. |
| aluminium foil | Regulation (EC) No 1935/2004 | complies. |
| aluminium foil | n.a. | complies with EN 602. |

(*) Regulation (EU) No 10/2011 was amended by Regulations 321/2011, 1282/2011, 1183/2012, 202/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213, 2018/831, 2019/37, 2019/1338, 2020/1245, 2023/1442 and 2023/1627. Reference to Regulation 10/2011 in this document includes these amendments unless noted otherwise.

(**) The term "used" refers to intentional presence in our raw materials or added during manufacturing. We cannot exclude trace impurities or incidental contaminants.

## 2. Further details on EU food contact compliance.

### a. Overall Migration Limit

In the context of food contact compliance, products of similar composition have been submitted to overall migration testing and were found to comply with the overall migration limit of 10 mg/dm² in test conditions of 10 days at 40°C in simulants A (3% acetic acid), B (10% ethanol) and D2 (vegetable oil) or simulant D2 substitutes (iso-octane and 95% ethanol).

### b. Specific restrictions on substances in plastics.

The following table list the ingredients of our plastic raw materials which are authorised in Regulation (EU) No 10/2011 with a specific migration limit or other restriction:

**table 4 – specific restrictions on plastics under Regulation (EU) No 10/2011.**

| No. | PM ref. | Substance name | CAS Nr. | Restriction (**) | Status (table 5) |
|---|---|---|---|---|---|
| 223 | 13630 | butadiene | 106-99-0 | SML = ND; DL = 0.01 mg/kg<br>QM = 1 mg/kg | 5 |
| 263 | 15760 | diethylene glycol | 111-46-6 | SML(T) = 30 mg/kg | 5 |
| 227 | 16990 | ethylene glycol | 107-21-1 | SML(T) = 30 mg/kg | 5 |
| 129 | 17020 | ethylene oxide | 75-21-8 | SML = ND; DL = 0.01 mg/kg<br>QM = 1 mg/kg | 3 |
| 98 | 17260 | formaldehyde | 50-00-0 | SML(T) = 15 mg/kg | 5 |
| 282 | 18430 | hexafluoropropylene | 116-15-4 | SML = ND; DL = 0.01 mg/kg | 5 |
| 291 | 19150 | isophthalic acid | 121-91-5 | SML(T) = 5 mg/kg | 5 |
| 239 | 19975 | melamine | 108-78-1 | SML = 2.5 mg/kg | 5 |
| 823 | 24889 | 5-sulphoisophthalic acid, salts | - | SML = 5 mg/kg | 5 |
| 785 | 24910 | terephthalic acid | 100-21-0 | SML(T) = 7.5 mg/kg | 5 |
| 132 | 26140 | vinylidene fluoride | 75-38-7 | SML = 5 mg/kg | 5 |
| 398 | 35760 | antimony trioxide | 1309-64-4 | SML = 0.04 mg/kg (Antimony) | 5 |
| 384 | 40000 | 2,4-Bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert butylanilino)-1,3,5-triazine | 991-84-4 | SML = 30 mg/kg | 3 |
| 658 | 52000 | dodecylbenzenesulphonic acid | 27176-87-0 | SML = 30 mg/kg | 5 |
| 433 | 68320 | octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate | 2082-79-3 | SML = 6 mg/kg | 3 |
| 505 | 86480 | sodium bisulphite | 7631-90-5 | SML (T) = 10 mg/kg (SO2) | 5 |
| | | undisclosed aluminium compound(s) | | SML(T) = 1 mg/kg (Aluminium) | 5 |
| | | undisclosed zinc compound(s) | | SML(T) = 5 mg/kg (Zinc) | 3 |

| | | | | | |
|---|---|---|---|---|---|
| | | isocyanate | | SML(T) = ND; DL = 0.01 mg/kg QM = 1 mg/kg (free NCO) | 10 |
| | | primary aromatic amines | | SML(T) = ND; DL = 0.01 mg/kg | 10 |

(**) Restrictions can be a specific migration limit (SML), a maximum concentration (QM) in the plastic, a maximum quantity per surface area (QMA), or a 'no detectable migration' (ND) requirement at a certain detection limit (DL). Suffix (T) indicates a combined restriction for 2 or more substances.

The above list of restricted substances is complete to the extent that accurate information was received from our raw material suppliers. The status with regard to the latest amendments of Regulation 10/2011 is as follows:

- Amendments up to 2020/1245 : fully covered by Table 4.
- Amendment 2023/1442: not yet covered by Table 4. Note that our product is a finished FCM; a transition period until 1 Feb. 2025 applies.
- Amendment 2023/1627 : fully covered by Table 4.

In absence of further studies, this list can be considered as an overview of the potential extractables and leachables from our product which are of toxicological interest. The limits and other restrictions indicated constitute a maximum acceptable daily dosage per person for a long-term use of 6 dm² of our product per day (assuming actual migration levels match the limit). This is still several orders of magnitude below a real safety limit for these substances.

### c. Compliance with specific restrictions on substances

Table 5 here below summarizes our compliance assessment for the restricted substances listed in table 4 above:

**table 5 – compliance assessment for substances listed in table 4.**

| Status (table 4) | compliance status |
|---|---|
| 3 | cannot exceed the limit even if total quantity migrates |
| 5 | compliance is confirmed by our supplier |
| 10 | finished product complies when the curing is complete |

Contact us for more details on this compliance assessment if needed.

## 3. Environmental Compliance

Our product is manufactured in compliance with Directive 94/62/EC on Packaging and Packaging Waste, as amended. More specifically, the combined total amount of Lead, Cadmium, Mercury and hexavalent Chromium in above-mentioned material does not exceed 100 ppm.

In addition we can confirm that our product is made of plastics and 'combustible' aluminium which, according to Annex B of EN standard 13431:2004 provide a positive calorific gain upon incineration.

When used by itself, our product meets the requirements of EN 13430:2004 on packaging recoverable by material recycling, on condition that it is verified to fulfil all relevant local regulations and provided that appropriate facilities exist where the packed product is put on the market.

With regard to the requirement on source reduction we point to Table 2 of EN 13427:2004 where it is explained that this assessment needs to be made at the level of the complete packaging system i.e. primary + secondary + tertiary packaging; consequently it is out of our control.

## 4. BSE/TSE

Throughout the plastics converting industry, certain low-level additives which are based on fatty acids/esters/alcohols that are derived from animal fats (tallow) are in widespread use; the use of these additives is generally considered to be unavoidable in many different types of plastics.

However, it has to be pointed out that:

- these substances are approved for food-contact use.

- Regulation (EC) No 999/2001 and its amendments assure that Specified Risk Materials (SRM) are removed prior to production of the materials of animal origin from which the above-mentioned substances are derived.
- the production of these additives is subject to very severe processing conditions that meet or exceed the recommendations for complete inactivation of TSE agents.

We therefore are certain that no danger for human health can result from the use of the above-mentioned additives and, by extension, our product.

## 5. Containers for pharmaceutical preparations

This product has not been assessed for compliance with the US or EU Pharmacopoeia.

## 6. Absense of chemical substances

Based on the information available to us, the following substances are not intentionally used in our raw materials nor added during manufacturing. Therefore our product is not expected to contain:

- acrylamide
- allergens listed in Annex II of Regulation (EU) No 1169/2011 as amended
- azodicarbonamide and semicarbazide
- asbestos
- brominated flame retardants
- substances intended to function as biocides and fungicides incl. dimethyl fumarate, paraben
- Bisphenol A, Bisphenol S
- Bisphenol A Diglycidyl Ether (BADGE), Bisphenol F Diglycidyl Ether (BFDGE) or Novolac Glycidyl Ethers (NOGE)
- dioxins
- genetically modified organisms (GMO) or products containing GMO
- mineral oil solvents not listed in Reg. 10/2011, other mineral oil saturated hydrocarbons (MOSH), mineral oil aromatic hydrocarbons (MOAH)
- natural rubber or natural rubber latex
- nonylphenol or nonylphenol ethoxylate
- oxo-degradable substances or substances making our product oxo-degradable
- ozone depleting substances according to the Montreal Protocol
- perfluoro-octanoic acid (PFOA), perfluoro-nonanoic acid (PFNA), perfluoro-hexane sulfonic acid (PFHxS), perfluoro-octane sulfonic acid (PFOS), perfluoro-alkyl phosphate esters (PAPs), perfluoro-alkyl carboxylic acids (PFCAs) and other perfluoro-alkyl acids (PFAA).
- photo-initiators, including benzophenone, benzophenone derivatives, isopropyl thioxanthone (ITX), etc.
- phthalate plasticizers
- phthalates used as technical support agent in polymer catalysis
- polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE)
- polychlorinated biphenyls (PCB)
- polycyclic aromatic hydrocarbons (PAH)
- post-consumer recycled waste
- PVC or PVDC
- titanium acetyl acetonate (TAA) or acetyl acetone
- triclosan
- UV-curing components

The absence of these substances has not been confirmed by testing. We cannot exclude trace impurities at insignificant levels resulting from incidental contamination or from impurities in precursors to our raw materials.

## 7. Disclaimer

This declaration is given in good faith and to the best of our current knowledge. It only covers the food contact compliance status of our product as it leaves our premises and does not imply any conclusions regarding technical aspects of the use of our product nor any unforeseen interactions of our product with the packaging process or the filling good.

This declaration replaces all previous declarations for the same specification/product. It remains valid until a change in the legislation or new scientific information change the legal status. At such time we will inform our customers accordingly.



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