

Regulatory Data Sheet

Extruded Tubing

ABL 00610 F0

PLASTIC FORMULATION
uncoloured

FOOD CONTACT ⁽¹⁾

US:

Is in compliance with F.D.A.: 21 CFR

- 177.1520 Olefin Polymers

EU:

Is in compliance with Regulation (EC) No. 1935/2004 of the European parliament and of the Council on materials and articles intended to come into contact with food.

Has been manufactured in accordance with the relevant requirements of Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Is in compliance with Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food and amendments (i.e. up to the date of issuance of this Regulatory Data Sheet).

All composing ingredients are listed in Annex I of Commission Regulation (EU) No. 10/2011, or otherwise authorized in accordance with the requirements laid down in this regulation.

Contains the following substances regulated with a specific migration limit:

aluminium compounds SML = 1mg/ kg (expressed as Al)

Does not contain intentionally incorporated dual use additives which are subject to disclosure of adequate information as described in Annex IV of Commission Regulation (EU) No. 10/2011.

No overall (OML) migration testing was performed on this material.

Specific (SML) migration testing (worst case) was performed on a representative sample:

Sample size: S/V ratio of 6

Food simulants: B

Test conditions: 4 hours at 100°C

The specific migration limit (SML) was not exceeded. The results of this test do not exclude the possibility that this material will still comply under other test conditions.

Please note that it is the responsibility of every actor within the supply chain to ensure compliance to the existing Regulations for every step under his responsibility.

Since Tekni-Plex Europe nv is not always informed of the conditions under which its products are used or processed, it cannot make any other guarantees of compliance other than towards the composition. It remains the responsibility of the food packager to ensure the suitability of our product for a specific use with a specific type of food through testing.

(1) Declaration based on certificates received from our suppliers.

The information contained herein is to our knowledge accurate and reliable as of the date of publication and for the mentioned product as manufactured by Tekni-Plex Europe nv. It is the customer's responsibility to inspect and test our products in order to satisfy himself as to the suitability of the products for the customer's particular purpose. The customer is also responsible for the appropriate, safe and legal use, processing and handling of our products. Tekni-Plex Europe nv shall not be under a duty to notify you of any changes to the regulations.

Insofar as products supplied by Tekni-Plex Europe nv are used in conjunction with third party materials, it is the responsibility of the customer to obtain all necessary information relating to the third party materials and ensure that Tekni-Plex Europe nv's products when used together with these materials are suitable for the customer's particular purpose. No liability can be accepted in respect of the use of Tekni-Plex Europe nv's products in conjunction with other materials. The information contained herein relates exclusively to our products when not used in conjunction with any third party materials.

PHARMACEUTICAL USE ⁽¹⁾

US:

This raw material has passed tests according to and is in compliance with:

- USP <87> "Biological Reactivity, In Vitro, Class VI"
- USP <88> "Biological Reactivity, In Vivo, Class VI"
- USP <661> "Containers - Plastics"
- USP <661.1> "Plastic Materials of Construction"

It is the responsibility of the manufacturer of the finished article to ascertain through appropriate testing that all relevant requirements for the intended use are met.

EU:

This raw material has been tested against the following monographs of the European Pharmacopoeia:

- Monography 3.1.3 "Polyolefines"
- Monography 3.1.6 "Polypropylene for containers and closures for parenteral preparations and ophthalmic preparations"

The composing raw material is in compliance with the following monographs of the European Pharmacopoeia:

- Monography 3.2.2 "Plastic containers and closures for pharmaceutical use"

It has to be recognized that these tests have been carried out with the raw material as such.

It is the responsibility of the manufacturer of the finished article to ascertain through appropriate testing that all relevant requirements for the intended use are met.

ELEMENTAL IMPURITIES ⁽¹⁾

During the manufacturing process of this product, we neither use materials which contain nor intentionally incorporate any Class 1, 2A, 2B or 3 elements as listed in the ICH Q3D Guideline on Elemental Impurities (December 2014).

Incidental presence of metal contaminants is not tested.

HEAVY METALS ⁽¹⁾

Complies with CONEG Regulations on heavy metal content (the cumulative content of Pb, Cd, Hg and Cr(VI) does not exceed 100 ppm).

Complies with Commission Directive (EU) No. 94/62/EC and amendments (i.e. up to the date of issuance of this Regulatory Data Sheet).

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REACH ⁽¹⁾

Does not contain any substances as part of the formulation which are classified carcinogenic, mutagenic, toxic to reproduction or dangerous for the environment, according to Directive 67/548/EEC as amended and/or Regulation (EC) No. 1272/2008 as amended and/or Regulation (EC) No. 1907/2006 as amended (i.e. up to the date of issuance of this Regulatory Data Sheet).

Does not contain SVHC substances in concentrations exceeding the legal threshold of 0,1% w/w, as published on the ECHA candidate list, current edition at the date of publication of this datasheet.

Since the presence of these substances are not to be expected under normal and foreseeable circumstances, Tekni-Plex Europe nv does not actively check their absence.

Tekni-Plex Europe nv will actively inform its customer base in case ingredients that are part of the formulation become listed.

BSE/TSE ⁽¹⁾

All ingredients are manufactured in accordance with the Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMA/410/01 Rev. 3 – July 2011) adopted by the Committee for Proprietary Medicinal Products (CPMP) and by the Committee for Veterinary Medicinal products (CVMP).

We therefore state that these materials are to be considered safe to use in food applications with respect to BSE and TSE transmissions.

COSMETIC APPLICATIONS ⁽¹⁾

Our product mostly finds its application in the packaging industry. It is a 100 % plastic material and not a cosmetic product, therefore Tekni-Plex Europe nv cannot state a full compliance with the Cosmetic Regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products and later amendments (up to the date of issuance of this Regulatory Datasheet). Based on certifications of suppliers we inform our customers that the following substances are used which are listed in Annex II (prohibited substances) and Annex III (restricted substances):

- Phthalate

These substances are embedded in the polymer matrix and hence not in a form that they can be released to the environment/product. It is the responsibility of the end consumer to test the migration of above mentioned substances in the end product in contact with the plastic material. Tekni-Plex Europe NV does not know the exact formulation of the end product and hence cannot provide this information to the customer.

Tekni-Plex Europe nv does not perform analyses for those substances. Our products are produced under Good Manufacturing Practice. We do not expect any of the non-listed substances to be present in more than trace amounts.

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EPOXY DERIVATIVES ⁽¹⁾

Does not contain any of the epoxy derivatives mentioned in the Commission Regulation (EC) No. 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food (BADGE, BFDGE, NOGE).

SAFETY OF TOYS ⁽¹⁾

The chemical composition complies with the restrictions set out in Directive 2009/48/EC (Safety of Toys), European Standard EN 71-3 (Safety of Toys) and EN 71-9 (Organic chemical compounds - Requirements).

ROHS ⁽¹⁾

The chemical composition complies with Directive 2011/65/EU and amendments (i.e. up to the date of issuance of this Regulatory Data Sheet) repealing Directive 2002/95/EC of the European Parliament and of the council on the restriction of use of certain Hazardous Substances in electrical and electronic equipment (RoHS).

CALIFORNIA PROPOSITION 65 ⁽¹⁾

None of the ingredients are expected to cause any contravention of the regulation of Safe Drinking Water and Toxic Enforcement Act of 1986, or the California Proposition 65 (current version).
Since the presence of these substances is not to be expected under normal and foreseeable circumstances, Tekni-Plex Europe nv does not actively check their absence.

CONFLICT MINERALS ⁽¹⁾

The above compound is a 100% synthetic product. Minerals do not form an integral part of the formulation, nor are minerals used in supporting or adjuvant production processes.
Based on the above, we can safely assume that minerals, especially conflict minerals, are not present in the above compound. Hence we can state that the 2010 Frank-Dodd Wall Street Reform and Consumer Protection Act (more specifically Title XV section 1502) and the Regulation (EU) 2017/821 of the Parliament and of the Council and future amendments are not directly applicable to this compound, nor to the products produced, using this compound.

Incidental presence of metal contaminants is not tested.

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ABSENCE OF SUBSTANCES AND CHEMICALS ⁽¹⁾

Based on our suppliers' certifications on the materials used for the above compound, we can safely state that the following substances are either not intentionally used or added to the finished product:

- Allergens
- Asbestos
- Azo dyes and pigments
- Benzophenone
- BHA/BHT
- Biocides
- Bisphenol A
- Dimethylfumarate
- Dioxine
- Formaldehyde
- Glycol ethers
- GMO
- Latex
- Melamine
- Nanomaterials
- Nitrosamines
- Organotin compounds
- Ozone depleting substances
- Perfluor compounds (PFOS/PFOA)
- Persistent Organic Pollutants (POP)
- Phthalates*

* DEP, DEHP, DIBP may be used in catalyst system which may result in traces of phtalates, however in concentrations below 1 ppm.

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