

11977-N

Food contact information

Ampacet **11977-N** masterbatch has been produced according to the good manufacturing practices (GMP) n°2023/2006 and comply with the relevant requirements of the Framework Regulation (EC) n°1935/2004. Moreover Ampacet **11977-N** masterbatch is composed of ingredients that meet the purity criteria of the following international food contact regulations:

EUROPE: Monomers, starting substances and additives comply with the relevant requirements of Plastics Regulation (EU) n°10/2011 as amended

The pigments contained in this masterbatch meet the purity requirements of EC Resolution AP(89)I.

According to the latest declarations of our suppliers, we can indicate the presence of following intentionally added substances which are subjected to restrictions:

Restrictions of use

| Specific Migration Limits | Substance Identification* | Max Content in the Masterbatch |
|---------------------------|---------------------------|--------------------------------|
| 6mg/kg | 68320 | 50ppm |
| 6mg/kg | 94960 | 2363ppm |
| 1mg/kg | Aluminum | 2.6% |
| 5mg/kg | Zinc | 1199ppm |

According to our suppliers' declarations, Ampacet masterbatch **11977-N** does not contain substances considered as migrating dual use additives (DUA). We cannot exclude the presence of traces of other metals listed in the Annex II as impurities coming from our raw materials.

Others prescriptions limit the use of this masterbatch at **10%** in food contact applications.

* Identification can be Food Contact Material number (FCM), Plastic Material reference number (Pm/Ref), Name, Group Restriction number according to (EU) n°10/2011 or Dual Use Additive E number according to (EU) 1338/2008.

U.S.A.: This MB is composed of ingredients that are regulated as acceptable under the following paragraphs of Title 21 of the Code of Federal Regulations (2021): §177.1520(c)2.1, 3.1a; §178.

Restrictions of use

| Allowed content in the final article | Food types (Table 1 §176.170) | Conditions (Table 2 §176.170) |
|--------------------------------------|-------------------------------|-------------------------------|
| 10% | I-IX | C-G |

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Regulations information

We received the confirmations from our suppliers that their products used in Ampacet **11977-N** do comply with the requirements applicable to masterbatches laid down in:

- European Directive **94/62/EC** on Packaging and Packaging waste and specifically Article 11 that requires a maximum concentration level of lead, cadmium, mercury and hexavalent chromium present in packaging or packaging components not exceeding 100 ppm by weight.
- European Commission Delegated Directive **2011/65/EU** on the restriction of the use of certain hazardous substances in electrical and electronic equipment (**RoHS**) as amended.
- European Directive **2000/53/EC** on end-of life vehicles.

The recommendations or regulations mentioned above refer to the final materials and articles. Therefore, it is the responsibility of the converter or the company that markets the final material or article to guarantee its compliance under actual and foreseeable conditions of use, and to check it on a regular basis.

Pharma/medical applications

Our masterbatch **11977-N** has not been specifically developed for pharmaceutical or medical applications. Therefore, we do not support the utilization of this product in these applications.

Drinking water applications

This masterbatch **11977-N** has not been designed for drinking water applications needing agreements such as KTW (Kunststoffe im Kontakt mit Trinkwasser) or ACS (Attestation de Conformité Sanitaire), and will not be supported by Ampacet for this type of applications.

If you need a masterbatch solution for KTW or ACS certifications for materials and accessories ensuring the transport of water intended for human consumption, please contact your Ampacet Technical Service Representative.

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Reach information

Ampacet masterbatch **11977-N** can be processed either inside or outside of European Union. Location of the plants can be found at the following link: <https://www.ampacet.com/about-ampacet/locations/europe/>.

Therefore, if your delivery plant is inside the European Union, the lots of masterbatch **11977-N** that Ampacet will supply you with will only be produced with raw materials that are covered by a REACH registration. However, if your delivery plant is outside the European Union, we would like to draw your attention to the fact that the REACH registration status of the substances used to manufacture this masterbatch has not been specifically reviewed; hence we do not support the lots of **11977-N** we will supply you with, as part of a REACH compliant use.

Moreover, this masterbatch does not contain substances included in candidate list of Substances of Very High Concern (**SVHC**) (January 17, 2023 and future inclusions ⁽¹⁾) in quantities exceeding the ECHA thresholds of **0.1% w/w** or substances listed in **Reach Annex XVII** ⁽²⁾, which means that we do not intentionally use them as raw materials. Therefore, we do not expect their presence.

- (1) **Note for SVHC:** Ampacet will inform its customers in case of inclusion of a new SVHC impacting the above mentioned masterbatch.
- (2) **Note for Annex XVII:** To identify substances regarded as dangerous according to 67/548/EEC or CLP, please refer to the masterbatch MSDS.

The recommendations or regulations mentioned above refer to the final materials and articles. Therefore, it is the responsibility of the converter or the company that markets the final material or article to guarantee its compliance under actual and foreseeable conditions of use, and to check it on a regular basis.

Last revised: 01/2023

AMPACET EUROPE S.A. - EUROPEAN HEADQUARTERS

Z.A.E. Wolser H, 130, L-3451 Dudelange, Luxembourg
+352 29 20 991 www.ampacet.com

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Various substances information

Ampacet **11977-N** masterbatch is not formulated with the following substances, which means that we do not intentionally use them as raw materials. However we cannot guarantee that there is no trace levels of these substances as impurity in this masterbatch since we do not test to verify the potential presence of these substances.

- Epoxy derivatives listed in Regulation (EC) n°1895/2005
- Recycled plastics according to Regulation (EC) n°2022/1616
- Allergens listed in Regulation (EU) n°1169/2011, Annex II
- Ozone depleting substances listed in regulation (EC) n°1005/2009
- Antimony trioxide
- Benzophenone
- Bisphenols (A, B, F, S)
- Dimethyl fumarate (DMF)
- Dioxin
- Epoxydized Soya Bean Oil (ESBO)
- Substances identified as endocrine disruptors at EU level in List I, last amended in Sep 2021⁽¹⁾
(<https://edlists.org/the-ed-lists/list-i-substances-identified-as-endocrine-disruptors-by-the-eu>)
- Formaldehyde ⁽²⁾
- Genetically modified organisms
- Isopropylthioxanthone (ITX)
- Latex
- Melamine / Cyanuric acid
- Organostannic compounds
- Parabens
- Pesticides / biocides / herbicides
- PFOA / PFOS / PFCA
- Plasticisers such as adipates, phthalates
- Radioactive substances
- Semicarbazide

⁽¹⁾ **Note for 4-tert-butylphenol (CAS 98-54-4):** we cannot exclude traces of this substance as a potential NIAS coming from antioxidant broadly used in polyolefins . If this substance would be present, the quantity would not exceed few ppm.

⁽²⁾ **Note for formaldehyde:** This substance is not intentionally added in the masterbatch formulation. However, it should be noted that thermal emissions (like aldehydes, ketones and organic acids) are generated during process of polyolefins and other polymers under typical processing conditions.

This regulatory status summarizes most of the characteristics required in critical applications. Should you intend to use our masterbatch **11977-N** for other purposes and/or need complementary information or clarification, please contact your Ampacet representative.

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In determining acceptability of this product in your intended application, we recommend you consult the applicable regulations for complete details. It is the responsibility of the manufacturer of the final food contact article to ensure compliance of the article with any applicable requirement. This declaration is valid for two years or until next relevant regulatory change. Any updated Regulatory Status can be provided upon request.

EUROPEAN REGULATORY AFFAIRS
AMPACET EUROPE S.A.

Disclaimer:

Please note that it is the responsibility of the manufacturer of the finished food-contact material or article to ensure that a product is safe, lawful, and technically suitable for use in the applications of interest. The manufacturer of the finished food-contact* material or article containing this product as a component must confirm that any applicable limitations, specifications, or other restrictions (as specified above or in applicable regulations) are met by the finished food-contact material or article.

The information contained in this document is based on Ampacet's current knowledge and understanding about the product, which is based principally on available third party information, including technical literature and data on the product category and customer assurance statements provided by Ampacet's suppliers. Ampacet assumes no liability in connection with any use of the information contained in this document, and such information should be used at your own responsibility and risk. This document is also subject to the terms and conditions set forth in the invoice or other contract or shipping document issued by Ampacet with respect to any limitations on liability.

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