Criteria and justification for quality labels ‘Microplastic-Free Content’ and ‘Microplastic-Free Container’ issued by Microplastic Solution (MPS)

MICROPLASTIC solution®

Microplastic-Free Content

Microplastic-Free Container

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Content

1. Introduction

Microplastics are ubiquitous environmental pollutants and therefore, exposure through inhalation and ingestion is almost impossible to avoid[1]. It is however, possible to manage our exposure by examining and limiting contamination routes into alimentary products for human consumption. Although research on the toxicological effect of microplastics on human health is still in the preliminary phase, experimental studies suggest that toxicity involved with microplastic ingestion is both size- and concentration-dependent[2,3]. Microplastics below 10 µm are considered to have the highest implication for human health, according to the World Health Organization (WHO)[4]. To offer consumers a conscious choice in reducing their exposure to microplastics through ingestion, MPS presents the world's first Microplastic-Free certification, encompassing secondary microplastics down to 1 µm in diameter. The current document accounts for the rationale behind the two available quality labels *i.e.* 'Microplastic-Free Content' and 'Microplastic-Free Container', issued exclusively by SAS Microplastic Solution (MPS).

Microplastic-Free Content

Microplastic-Free Container

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2. Definitions

The definitions provided apply to “Microplastic-Free” products and packaging. This includes items from various sectors such as food and non-food (e.g., cosmetics), fashion, home and garden (including compost, fertilizers, or soil additives), and leisure.

2.1. Product

In this certification scheme, products are defined as the goods or contents of a consumer good. Examples include a piece of clothing, foodstuff, tableware, cosmetics, or cleaning items (detergents).

2.2. Packaging

Packaging refers to containers, wrappings, and outer packaging of a product or a semi-finished product. Examples include sales packaging or cardboard packaging used for shipping or transporting consumer goods.

2.3. Consumer

A consumer is the end user who no longer resells the consumer goods in the form delivered to them on a commercial basis.

2.4. Polymer

The term polymer describes chemical compounds consisting of chain or branched molecules (macromolecules), which in turn consist of a large number of identical or similar units known as monomers.

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2.5. Plastic

Plastics are organic macromolecular compounds obtained through processes such as polymerization, polycondensation, or polyaddition, or by chemically modifying natural molecules. Other substances or materials may be added to these compounds. The starting materials for plastics typically have a natural basis (fossil raw materials), which are chemically processed to form polymeric materials. Plastics are categorized into elastomers, thermoplastics, and duroplastics. The term plastic refers to plastic of any type and origin.

2.6. Microplastic

Microplastics refer to solid polymer particles, which may include additives or other substances. According to ISO/TR 21960:2020, microplastics are distinguished as follows:

1) Microplastics: Solid plastic particles insoluble in water with dimensions between 1 µm and 1000 µm (1 mm).
2) Large Microplastics: Solid plastic particles insoluble in water with dimensions between 1000 µm and 5000 µm (5 mm).

If not otherwise stated, 'microplastic' refers to both primary- and secondary microplastics.

2.7. Primary microplastic

Primary microplastics are intentionally manufactured small plastic particles, often used in products like cosmetics, detergents, or industrial abrasives.

2.8. Secondary microplastic

Secondary microplastics are particles that result from the fragmentation of larger plastic debris due to environmental factors such as UV radiation, physical abrasion, or chemical degradation.

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2.9. Blank correction

Blank correction refers to the process of subtracting the amount of microplastics found in a procedural blank experiment from the total microplastic count in a sample. This step ensures that the microplastic measurements accurately reflect only those particles originating from the sample itself, excluding any contamination introduced during the experimental procedure. Learn more about the specifics at https://www.microplasticsolution.com/microplastic-detection.

2.10. Recovery correction

Recovery correction is the process of adjusting the measured count of microplastics to account for any loss of particles that may have occurred during the experimental protocol. This correction ensures that the final microplastic count accurately represents the original amount present in the sample before any losses occurred. Learn more about the specifics at https://www.microplasticsolution.com/microplastic-detection.

3. Product requirements

For a product to be considered 'Microplastic-Free', the mass concentration of microplastics (primary- and secondary microplastics) must not surpass 0.01 PPB (0.01 µg/kg) within the product.

3.1. Microplastic-Free Content

The concentration of microplastics of any polymer type and of any nature or origin, within the product must not exceed 0.01 µg/kg (0.01 PPB), following blank- and recovery correction. This includes unintentionally added secondary microplastics of any source.

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3.2. Microplastic-Free Container

The concentration of microplastics of the same polymer type as the container-to-product medium (packaging in contact with the product) must not exceed 0.01 µg/kg (0.01 PPB), following blank- and recovery correction. This includes unintentionally released secondary microplastics released from the packaging itself.

4. Justification

'Microplastic-Free' ('Content' and 'Container') certification is applicable to all products, including non-alimentary goods. The current criteria for certification are independent of the nature of the product in question. The certification criteria are related to contemporary research on microplastic toxicity and environmental exposure. The definition of 'Microplastic-Free' is introductory and may have to be reassessed in the future. However, the 'Microplastic-Free Content' as well as the 'Microplastic-Free Container' quality labels are world-first attempts to help consumers control and decrease their microplastic consumption.

4.1. Microplastic-Free

Criteria to obtain 'Microplastic-Free' certification require microplastic mass concentrations below 0.01 PPB (0.01 µg/kg). The microplastic mass concentration of 0.01 µg/kg is thousands of times lower than environmental relevant concentrations[3,5] (slightly higher than those in the surface water but remarkably lower than that in the soils[6]) and much lower than those applied in rodent animal in vivo experiments[7]. Polystyrene microplastics at concentrations 2,500-5,000 times higher than the accepted threshold for 'Microplastic-Free' certification, directly spiked onto liver and brain organoids, demonstrated slight hepatoxicity[2,3]. These analyses demonstrated that microplastic toxicity is both size- and concentration-dependent.

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Alimentary products that meet 'Microplastic-Free Content' certification guarantees that microplastic exposure resulting from the ingesting 5 kg of sustenance (including drinking water) is more than 10,000 times lower than the exposure from indoor atmospheric inhalation[8,9] (an exposure route that cannot easily be mitigated). Ref [8]: daily dust ingestion estimated at 2.2 mg/day. Ref [9]: 4% of dust is of synthetic polymeric nature.

'Microplastic-Free Content' daily ingestion = (5kg * 0.01 µg/day) = 0.05 µg/day.

Daily inhalation = (2.2 mg/day[8]) * (0.04% [4% plastic][9]) = 0.88 mg/day = 880 µg/day

Ratio: difference in exposure from daily inhalation versus 'Microplastic-Free Content' ingestion = (880 µg/day) / (0.05 µg/day) = 11,760.

Existing microplastic studies on indoor air pollution do not consider particles < 10 µm[4], and as a result particle numbers may be underestimated by at least 150 times[10], however, total mass should barely be affected. The U.S. Food and drug administration (FDA) suggest that current scientific evidence does not demonstrate that levels of microplastics or nanoplastics detected in foods pose a risk to human health (FDA, 2024). the FDA underlines however, that "because there are no standardized methods for how to detect, quantify, or characterize microplastics and nanoplastics, many of the scientific studies have used methods of variable, questionable, and/or limited accuracy and specificity".

Like other threshold values for acceptable concentrations of contaminants or allergens, 'Free' does not indicate a value of 'zero', as this is generally unattainable (Example: gluten free = 20 PPM[11]) but is instead based on the tolerable level of the specific contaminant. If the threshold value is too stringent and cannot be met by manufacturers, consumers have no means of navigating between products. For contaminants where the long-term consequences of exposure

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are not fully understood (such as microplastic), threshold values are set very low as a cautionary measure (Example: pesticides in drinking water according to the European Union = 0.1 µg/kg[12]). For microplastics, a similar approach could be adopted.

For these reasons, we believe that the selected threshold value of 0.01 µg/kg of plastic is a realistic and safe threshold value for human consumption, until/if proven otherwise.

5. Sampling

For verification testing, the applicant (usually the manufacturer or seller) must provide test samples of a volume appropriate to the sample matrix for each product intended for certification. The specific sample volume will be determined through initial consultation between the applicant and Microplastic Solution (MPS), and will correspond to typical consumption amounts. For example, with tea products, testing will be performed on a prepared cup of tea of standard volume rather than testing the dry tea leaves and extrapolating. Samples must be provided in original, unopened packaging to ensure testing integrity. Additionally, a list of ingredients for the product must be submitted. The applicant is responsible for covering the shipping costs of these samples.

6. Test procedure

Microplastic Solution (MPS) carries out all analysis and test after receipt of the test samples, including blank- and recovery corrections. Note: Drinking water samples are not blank corrected as by ISO/DIS 16094-2. Chemical signature (polymer type) of microplastics down to 1 µm in diameter is determined using automated Raman microspectroscopy. Learn more about our analyses at https://www.microplasticsolution.com/microplastic-detection. For any product of

any matrix type, two individual replicate samples are prepared and analyzed. For each replicate sample, three subsamples are analyzed by Raman microspectroscopy in a Helix model pattern. The investigated area corresponds to 7.2% of the total filter area. The final microplastic concentration is based on the average content of the two replicate samples, following quality controls, data extrapolation and normalization.

6.1. Test report

The test report must comply with the following information:

- Name and address of the manufacturer.
- Name and address of the applicant (if different from the manufacturer).
- Test basis (certification scheme) with date of issue.
- Type of test (e.g., type test, additional test, etc.).
- Test date.
- Results and evaluation of the test.
- Name and signature of the individual responsible for the test.
- Product description, including picture and dimensions, to clearly identify the test sample.

7. Product classification

'Microplastic-Free' products that differ in essential certification-relevant characteristics are defined as different 'models'.

Examples of certification-relevant properties that define a model include:

- Ingredients and composition

- Container type
- Production site
- Source of ingredients

8. Legal rights

SAS Microplastic Solution (MPS) provides exclusive right to the use, distribution and sub-licensing of the 'Microplastic-Free Content' and 'Microplastic-Free Container' certification and quality labels, protected under the eSoleau INPI decree (DSO2024011868 and DSO2024011869).

8.1. labelling and identification

Products for which the right to use the certification and quality labels 'Microplastic-Free Content' and 'Microplastic-Free Container' has been granted, must be marked with the relevant certification mark and the associated registration number.

Certification	Label	eSoleau INPI decree
Microplastic-Free Content		DSO2024011868
Microplastic-Free Container		DSO2024011869

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8.2. Publications

All certificate holders can be viewed on the homepage of microplasticsolution.com. Microplastic Solution (MPS) is responsible for updating its own website. Manufacturers, users, and consumers can use this resource to obtain information on certified products.

8.3. Validity of certificate

The certificate is valid for 12 months (one year) after the date of certification issuance. The period of validity is shown on the certificate report. On expiry of the certificate, the right to use the mark also expires.

8.4. Renewal of certificate

To extend certification beyond the date indicated on the certificate, Microplastic Solution (MPS) or a sub-licensed third party must produce a positive test report before the validity expires. Microplastic Solution (MPS) will conduct the conformity assessment based on this test report.

8.5. Expiry of certificate

If a new evaluation for conformity is not completed in a timely manner before the end of the validity period, the right to use the certification mark and the associated registration number will expire automatically, without the need for explicit notification from Microplastic Solution (MPS).

Additionally, certificates may expire under the following circumstances:

- The certification mark is misused by the certificate holder.

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- The requirements outlined in the certification scheme or its accompanying documents are not met.
- Certification fees are not paid by the due date.
- The prerequisites for issuing the certificate or confirming acceptability are no longer fulfilled.
- The protocol, ingredients or source of ingredients of the product changes.

8.6.Licensure fee

The minimum licensure fee for a 'Microplastic-Free' certification is €5,999.95 (€499.95/month), but it may increase depending on the complexity of the sample matrix. This fee is negotiated between Microplastic Solution and the client before the analyses begin and the samples are shipped. The annual renewal fee for the certification is the same as the initial or previous year's fee due to the need for a new and comprehensive analysis. The renewal fee can be renegotiated by either party after each annual renewal. An initial screening test for a single sample to estimate compliance is available from €499.95 but it may increase depending on the complexity of the sample matrix. The initial screening test can be applied only once to a unique model product, unless otherwise agreed upon between the two parties. For valid licensing, the licensure fee applies to a single, unique model.

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