Sub-statement on the potential risk(s) from exposure to microplastics: Inhalation route

Microplastics - Inhalation route - COT evaluation

In this guide

In this guide

84. NMPs are widespread, they are either intentionally added to products or occur as a result of plastics being fragmented down into smaller sizes by natural processes such as wear, weathering and corrosion. There is no internationally agreed definition of what a microplastic is, however, the most widely used size range is from 0.1-5,000 µm. Plastic particles that are smaller than the lower range are considered nanoplastics (i.e. 1 nm – 0.1 µm).

85. Microplastics can have a wide range of physicochemical properties, depending on the primary purpose of the plastic; however, these properties may not be the same in secondary microplastics, where fragmentation has occurred as a result of natural processes (and as such the MPPs are not considered pristine).

86. Analytical methodology is currently limited to Fourier-transform infrared spectroscopy (FT-IR), Nile Red, quantitative nuclear magnetic resonance(qNMR), Micro-Raman spectroscopy and mass-spectroscopy.

87. There are no standardised testing methods for different matrices such as air, soil, food and water; the available methods have their own associated limitations, and suitable reference materials are not currently available. Furthermore, no single technique is suitable for all plastic types and/or for all particle sizes or shapes. Using a suite of methods or generation of new techniques may be necessary to fully assess microplastics.

88. In terms of the toxicity of NMPs, there are no studies suitable for identification of No Observed Adverse Effect Level (NOAEL) for any polymer type (with the possible exception of PET powder at 2,500 mg/kg bw/day in rats for oral exposure as reported by Merski et al., 2008, however, this study has several limitations and was conducted using the oral exposure route). Available data from the European Chemical Agency Registration, Evaluation, Authorisation and Restriction of Chemicals (ECHA REACH) database relates only to the starting materials i.e. the monomers. Furthermore, variability in exposure routes must also be considered.

89. Comparing studies using different methodology and analytical techniques can be challenging as there is currently no standardization for characterizing and testing microplastics.

90. Contamination with airborne microplastics or cross-contamination of samples may also affect the interpretation of studies, so suitable control samples may be difficult to obtain.

91. Most toxicity studies have been performed with pristine particles, mostly polystyrene; however, these may not be representative of what is present in the environment as the particles have not undergone degradative processes or contain any additional pollutants that attach to the microplastic. There are no specific reference materials that can be used and batch to batch variation can also occur.

92. Currently a full risk assessment on the potential toxic effect(s) of NMPs could not be carried out due to several data gaps including:

- The unavailability of harmonised methodologies to characterise, quantify and identify NMPs.

- The lack of toxicokinetic and toxicity data in general. There are no studies suitable for the identification of NOAELs for the different polymer types except possibly for PET powder by the oral route at 2,500 mg/kg bw/day in rats, (see paragraph 88), which had a number of limitations (e.g. particle size and count were not determined/reported).
- The paucity of currently available data for microplastics and airborne exposure.
- The difficulty of performing an accurate exposure assessment.

93. For the reasons above, a case-by-case approach to risk assessments may need to be considered. This aligns with the conclusions reached by other authoritative bodies (WHO, 2022; Environment and Climate Change and Health Canada(ECC and HC), 2020; EU Science Advice for Policy by European Academies (SAPEA), 2019; EU Group of Chief Scientific Advisors; Scientific Advice Mechanism (SAM), 2019, as described in the COT overarching statement on the potential risks from exposure to microplastics; COT Statement 2021/02, paragraphs 101-129).