

*Appendix 16***Entry 78 – Rules on proving solubility**

This appendix lays down the permitted test methods and the test conditions to prove that a polymer is soluble for the purposes of entry 78. The tests shall be conducted by laboratories complying with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency or accredited to ISO 17025.

Permitted test methods:

1. OECD Guideline 120
2. OECD Guideline 105

The test shall be performed on a test material consisting of a polymer or polymers contained in or building a continuous coating on particles (“polymer particles”) comparable in terms of composition, form, size and surface area to the polymer particles present in the product or, if not technically feasible, to the polymer particles that are disposed of or released to the environment.

By way of derogation from the third paragraph, for polymer particles that have all dimensions greater than 0,25 mm or have a length to diameter ratio greater than 3 and are longer than 0,25 mm, the size of the polymer particles to be tested shall be reduced in accordance with OECD guideline 120, so that at least one dimension of the polymer particle or, for polymer particles that have a length to diameter ratio greater than 3 the length of the polymer particle, is between 0,125 mm and 0,25 mm. For polymer particles containing inorganic substances in addition to a polymer or polymers, such as polymer particles encapsulated with inorganic substances or polymer particles where a polymer is grafted onto an inorganic carrier, it shall be sufficient to demonstrate that the polymer meets the pass criterion. To this end, it is allowed to test the solubility of the polymer or the polymers prior to the formation of the polymer particles.

The conditions for the solubility test shall be the following:

- Temperature 20 °C
- pH 7
- Loading: 10 g/1 000 mL
- Test time: 24 h

Pass criterion: solubility > 2 g/L.’
