

EN

Annex

Substance	Test methods	Further specifications
<p>Polyhaloalkene</p> <p>EC Number 468-710-7</p> <p>CAS Number 754-12-1</p>	<p>(1) Transgenic rodent somatic and germ cell mutation assay (TGR) (OECD TG 488 / Test Method Regulation B.58).</p> <p>(2) In vivo mammalian alkaline Comet Assay (OECD TG 489)</p>	<p>(1) The test shall be conducted as follows:</p> <ul style="list-style-type: none"> - in mice treated for 28 days via inhalation (*); - the tissues (lung, liver, bone marrow) shall be harvested three days after cessation of treatment (**); - mutation frequency shall be assessed in lung, liver, and bone marrow; - germ cells from testes shall be sampled at both 3 days and seven weeks after cessation of exposure and stored for at least 36 months after the dossier is updated with the results of the test; - the testes cells shall be analysed for mutation frequency if positive test results are obtained for any of the somatic cells. <p>(2) The test shall be conducted as follows:</p> <ul style="list-style-type: none"> - in rats via inhalation (*); - the tissues (lung, liver, bone marrow) shall be harvested three days after cessation of treatment (**); - DNA damage shall be assessed in lung, liver, and bone marrow. <p>(*) In both tests, inhalation is the most appropriate route of administration due to the physico-chemical properties of the substance.</p> <p>(**) The reasons for tissue selection, equally applicable regardless of which test is performed, are as follows:</p> <ul style="list-style-type: none"> ▪ The lung is chosen due to exposure via inhalation as the initial site of contact with the body. ▪ Liver is chosen to study effects on a tissue that is exposed to systemically available substances and is a main site of metabolism. Moreover it is a slowly dividing tissue. ▪ The bone marrow is chosen because it is a rapidly dividing tissue.