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ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ¹	Expiry date of approval	Pro- duct type	Specific conditions
Difethialone	IUPAC Name: 3-[3-(4'-bromo[1,1'-biphenyl]- 4-yl)-1,2,3,4- tetrahydronaphth-1-yl]-4- hydroxy-2H-1- benzothiopyran-2-one EC No: Not available CAS No: 104653-34-1	976 g/kg The specification of purity is based on the combined concentration of both diastereoisomers (cis and trans).	30 June 2024	14	Difethialone is considered a candidate for substitution in accordance with points (a) and (e) of Article 10(1) of Regulation (EU) No 528/2012. The authorisations of biocidal products are subject to the following general conditions: 1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied. 2) Products shall only be authorised for use in Member States where at least one of the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 is satisfied. 3) The nominal concentration of difethialone in the products shall not exceed 25 mg/kg. 4) Products shall contain an aversive agent and a dye. 5) Products shall not be authorised in the form of tracking powder. 6) Products in the form of contact formulations, other than

¹ The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

					<p>tracking powder, shall only be authorised for use by trained professionals indoors in places not accessible to children or non-target animals.</p> <p>7) Only ready-to-use products shall be authorised.</p> <p>8) Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include for example the restriction to professional or trained professional use when possible and setting additional specific conditions per user category.</p> <p>9) Dead bodies and uneaten bait shall be disposed of in accordance with local requirements. The method of disposal shall be described specifically in the summary of the product characteristics of the national authorisation and be reflected on the product label.</p> <p>In addition to the general conditions, the authorisations of biocidal products to be used by the general public are subject to the following conditions:</p> <p>1) Products shall only be authorised for use in tamper-resistant bait stations.</p> <p>2) Products shall only be supplied with a maximum quantity of bait per pack of:</p> <p>a) For products against mice only:</p> <p>i) For grain, pellet or paste baits: 50 g.</p> <p>ii) For wax block baits: 100g.</p> <p>b) For products against rats only, or mice and rats:</p> <p>i) For grain, pellet or paste baits: 150 g.</p> <p>ii) For wax block baits: 300g.</p> <p>3) Products against <i>Rattus norvegicus</i> and <i>Rattus rattus</i> shall only be authorised for use indoors or in and around buildings.</p> <p>4) Products against <i>Mus musculus</i> shall only be authorised for use indoors.</p> <p>5) Products shall not be authorised for use in permanent or</p>
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				<p>pulse baiting treatments.</p> <p>6) Persons making products available on the market shall ensure that the products are accompanied by information on the risks associated with anticoagulant rodenticides in general, measures to limit their use to the minimum necessary and appropriate precautionary steps to be taken.</p> <p>7) Products in the form of loose bait formulations, such as grain or pellets, shall only be authorised in formulations that are supplied in sachets or other packaging to reduce exposure to humans and the environment.</p> <p>In addition to the general conditions, the authorisations of biocidal products to be used by professionals are subject to the following conditions:</p> <ol style="list-style-type: none"> 1) Products shall not be authorised for use in sewage, open area or waste dumps. 2) Products shall not be authorised for use in permanent or pulse baiting treatments. 3) Products shall only be authorised for use in tamper-resistant bait stations. 4) Persons making products for professional users available on the market shall make sure that these products are not supplied to the general public. <p>In addition to the general conditions, the authorisations of biocidal products to be used by trained professionals are subject to the following conditions:</p> <ol style="list-style-type: none"> 1) Products may be authorised for use in sewage, open area or waste dumps. 2) Products may be authorised for use in covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. 3) Products may be authorised for use in pulse baiting treatments. 4) Products shall not be authorised for use in permanent
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					baiting treatments. 5) Persons making products for trained professional users available on the market shall make sure that the products are not supplied to other persons than trained professionals.
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