

Section IIIA.8 Annex Point II.A. VIII	Measures necessary to protect man, animals and the environment	Official use only
	<p>Inhalation Unlikely to present an inhalation hazard unless excessive dust is present. Move to fresh air. Obtain medical advice immediately.</p> <p>Ingestion If swallowed, seek medical advice immediately and show this container or label.</p> <p>General advice In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).</p> <p>ADVICE FOR DOCTORS: Difenacoum is an indirect anti-coagulant. Phytomenadione, Vitamin K1, is antidotal. Determine prothrombin times not less than 18 hours after consumption. If elevated, administer Vitamin K1 until prothrombin time normalises. Continue determination of prothrombin time for two weeks after withdrawal of antidote and resume treatment if elevation occurs in that time.</p> <p>Emergency Measures to protect the environment</p> <p>Personal precautions Wear suitable protective clothing, gloves and eye/face protection.</p> <p>Environmental precautions Prevent further leakage or spillage if safe to do so.</p> <p>Methods for cleaning up Clean up promptly by sweeping or vacuum. Transfer to a suitable labelled container. Subsequently, wash the contaminated area with water, taking care to prevent the washings entering sewers or drains.</p>	<p>X</p> <p>X</p> <p>x</p>
<p>8.4 Possibility of destruction or decontamination following release in or on the following: (IIA, VIII.8.4)</p>		
<p>a. air</p>	<p>The pure active ingredient is produced in a closed vessel, and diluted in that vessel to make the master mix concentrate. The pure active ingredient is not stored or transported.</p> <p>Additionally, difenacoum has a very low vapour pressure, and decomposes at around 220°C and therefore does not boil.</p> <p>Hence, the risk of release of the active ingredient to atmosphere is negligible.</p> <p>The master mix concentrate is produced at a typical concentration of 2.5% active ingredient. (This is not an aqueous solution.) The master mix is transported, and may be stored, however this does not present a risk of release to air.</p>	
<p>b. water, including drinking water</p>	<p>The pure active ingredient is produced in a closed vessel, and diluted in that vessel to make the master mix concentrate. The pure active ingredient is not stored or transported. The manufacturing sites do not drain surface water to sewers, so there is no potential for contamination of water from the manufacturing process.</p> <p>In addition the very low water solubility of the active ingredient, and its affinity for soil means that any release into an environmental aquatic</p>	

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	<p>compartment will result in rapid partitioning to the solid phase, usually soil.</p> <p>Moreover, the master mix is not an aqueous solution, and the octanol-water partition coefficient is high, and hence the active ingredient will remain in the master mix. On site spillages of the master mix would be collected and used in the manufacture of product, hence exposure will be negligible.</p>	
c. soil	<p>The pure active ingredient is produced in a closed vessel, and diluted in that vessel to make the master mix concentrate. The pure active ingredient is not stored or transported. The manufacturing sites do not drain surface water to sewers, so there is no exposure to soil of the pure active ingredient.</p> <p>The master mix concentrate is not an aqueous solution, and the octanol-water partition coefficient is high, and hence the active ingredient will remain in the master mix. On site spillages of the master mix would be collected and used in the manufacture of product, exposure to soil in this event is also negligible.</p>	x
8.5 Procedures for waste management of the active substance for industry or professional users (IIA, VIII.8.5)	<p>Dispose of packaging, remains of unused product and dead rodents to certified waste disposal operator for incineration and licensed waste disposal site.</p> <p>Dispose of waste material by high temperature incineration.</p>	x
8.5.1 Possibility of re-use or recycling (IIA, VIII.8.5.1)	Where possible recycling of production and formulation waste within the production process is preferred to disposal or incineration. i.e. uncontaminated waste should be reused in production/formulation of next production batch.	
8.5.2 Possibility of neutralisation of effects (IIA, VIII.8.5.2)	Incineration is recommended.	
8.5.3 Conditions for controlled discharge including leachate qualities on disposal (IIA, VIII.8.5.3)	None	
8.5.4 Conditions for controlled incineration (IIA, VIII.8.5.4)	Incineration should only be performed in incineration plant regulated under the EU directive 2000/76/EC. The active substance is not a chlorinated organic not does it contain heavy metals. Under Directive 2000/76/EC, the incineration exhaust gases must be heated to 850°C for not less than 2 seconds. As regulated, oxygen content in the flue gas should exceed 10% v/v (or 6% if biomass incineration) measured for dry gas at 273 K and 101.3 kPa.	
8.6 Observations on undesirable or unintended side-effects (IIA, VIII.8.6)	The active substance in the form of baits with grain and/or other food stuff will be palatable to non-target species in sufficient quantity to produce toxic effects. The active substance will have the same toxic effect in non-target species as in target species. See Section B7.8.7.2 for details of effects on non-target species.	
8.7 Identification of any substances falling within the scope of List I or List II of the Annex to Directive	As a biocide not falling within list I, the a.i. must be under List II.	

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80/68/EEC (IIIA, VIII.1)		
	Evaluation by Competent Authorities	
<p style="text-align: center;">EVALUATION BY RAPPORTEUR MEMBER STATE</p> <p>Date SYKE 9.1.2008/STTV 15.1.2008 (compliance with the information of SDS and/or study results checked)</p> <p>Materials and methods</p> <p>Results and discussion</p> <p>Conclusion</p> <p>Reliability 0 (Not an experimental study)</p> <p>Acceptability Acceptable</p> <p>Remarks</p> <p>8.3 The text should be in accordance with the advice on first aid measures under point 4 in the SDS document if it is updated. It says that medical advice should be obtained immediately. Skin irritation is not mentioned neither supported by the data provided in the dossier.</p> <p>Eye irritation is not mentioned in the SDS document neither supported by the data provided in the dossier.</p> <p>Also for the inhalation hazard, the text should reflect the one in SDS. "Unlikely to present an inhalation hazard..." is not appropriate in this connection.</p> <p>..For ingestion, provide the same information as presented in the SDS document.</p> <p>8.3 suitable methods for cleaning up for accidental release to soil is missing (but in SDS there is 'absorb or cover with moist earth, sand or other non-combustible material').</p> <p>8.4 c) decontamination of contaminated soil when released to the soil due to an accident or misuse is missing.</p> <p>8.5 first sentence is applicable only for product, not for active substance. Active substance should be disposed of as hazardous waste in compliance with local and national regulations. Any disposal must comply with Local and National Requirements which are derived from the EU Directives 94/67/EC of 16 December 1994 on the incineration of hazardous waste and 2000/76/EC of 4 December 2000 on the incineration of hazardous waste. There are no foreseeable restrictions to the use of incineration for the destruction of wastes containing difenacoum.</p>		
<p style="text-align: center;">COMMENTS FROM ...</p> <p>Date <i>Give date of comments submitted</i></p> <p>Results and discussion <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i></p> <p>Conclusion <i>Discuss if deviating from view of rapporteur member state</i></p> <p>Reliability <i>Discuss if deviating from view of rapporteur member state</i></p> <p>Acceptability <i>Discuss if deviating from view of rapporteur member state</i></p> <p>Remarks</p>		