Section A2.10

Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Subsection		Official use only
2.10.1 Human exposure towards active substance		
2.10.1.1 Production		X
i) Description of process	It is to take in account that the active involved is an anticoagulant: it gains this property when chemical is completed coupling intermediate with 4-hydroxycoumarin. It is to be clear that only at this point the chemical begin an anticoagulant. In addition the active is used only to prepare anticoagulant solutions at 2,5% or other percentage. So all production processes, carefully follow three important steps: 1 - production of intermediate till last step with no anticoagulant properties, 2 - coupling of intermediate with 4-hydroxycoumarine to obtain the anticoagulant 3 - preparation of solution. Production follows, in sequence, preparation till last intermediate in various quantities. Right amount of this last intermediate is coupled with 4-hydroxycoumarin, in established conditions, to obtain in situ the anticoagulant	
ii) Workplace description	Closed system; Full PPE (gloves, coveralls, face-shield, respirator) when filling and for maintenance. No separate cleaning operation since vessel is used only for difenacoum production needed for 2,5% or other percentage solution preparation. Last step, including solution preparation, is achieved without any operator contact excluding only active and solution sampling for quality control, that are made on solution production so no contact with any kind of solid or powder product is possible. All operations are made inside appropriate closed vessels Production vessel are always the same. Production started around 1975 and since over 29 years no accidents of any kind happened: all production processes as well facilities were carefully studied.	
iii) Inhalation exposure	Production takes place in closed vessels by operator wearing full PPE including air-fed hood. Hence inhalation exposure is negligible as shown by operator monitoring.	X
iv) Dermal exposure	Production takes place in closed vessels by operator wearing full PPE including gloves and overalls. Hence dermal exposure is negligible as shown by operator monitoring	X

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2.10.1.2	**Intended use(s)**		
	1. Professional Users		
	i) Description of application process	1) Blocks are removed from container and placed in situ; 2) Remains of blocks are collected and placed in container for disposal	
	ii) Workplace description	Domestic, industrial, commercial, institutional or agricultural premises, sewers, drain, culverts and other infested sites	
	iii) Inhalation exposure	Negligible; Estimated in report "Human and Environmental Exposure Scenarios for Rodenticides -Focus on the Nordic Countries", to be 0.0278 mg/kg/day. However, this was from '' sweeping up", which is not a normal task conducted in sewers.	X
	iv) Dermal exposure	Negligible; Estimated in report "Human and Environmental Exposure Scenarios for Rodenticides -Focus on the Nordic Countries", to be 0.134 mg/kg bw/day	X
	2. Non-professional Users including the general public		
	(i) via inhalational contact	Negligible; Estimated in report "Human and Environmental Exposure Scenarios for Rodenticides -Focus on the Nordic Countries", to be 0.0278 mg/kg/day. However, this was from '' sweeping up", which is not a normal task conducted in sewers.	
	(ii) via skin contact	Negligible; Estimated in report "Human and Environmental Exposure Scenarios for Rodenticides -Focus on the Nordic Countries", to be 0.134 mg/kg bw/day	
	(iii) via drinking water	Negligible. There is no conceivable way in which drinking water could be contaminated	X
	(iv) via food	Negligible. There is no conceivable way in which food could be contaminated	X
	(v) indirect via environment	Negligible. The product is of low vapour pressure and negligible water solubility, formulated as a large solid block which is placed in a bait box or under other enclosure.	
2.10.2	**Environmental exposure towards active substance**	Product is of very low water solubility and low vapour pressure. It is used primarily indoors or in enclosed spaces e.g. sewers. Environmental exposure will be minimal and in environments where the transmission of serious human pathogens is the primary concern.	
2.10.2.1	**Production**		
	(i) Releases into water	Production is in closed vessel which is dedicated to difenacoum production. It is not washed out and there is no release to water via	

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	waste disposal	
(ii) Releases into air	Production is in closed vessel which is dedicated to difenacoum production. It is not washed out and there is no release to water via waste disposal Product is thermally stable, has a high melting point and a very low vapour pressure, so release into air will be minimal It is used primarily indoors or in enclosed spaces e.g. sewers. There is therefore no release to air	
(iii) Waste disposal	Production is in closed vessel which is dedicated to difenacoum production. It is not washed out and there is no release to water via waste disposal. Other vessels used for intermediates and finished products are similarly dedicated and not washed out. Cleaning is part of the production procedure as all wastes are put back into the formulation process. Operators wear PPE (coverall, boots and thick gloves) during the final mixing of the hot wax and dry mix and during the moulding stage.	
2.10.2.2 Intended use(s)		x
Affected compartment(s): water	Method of use is as follows: 1) Blocks are removed from container and placed in situ; 2) Remains of blocks are collected and placed in container for disposal The possibilities for water contamination are negligible due to uses, method of application and properties of the product, except in the case of sewer baiting, when remains can get washed into sewage.	
sediment	Method of use is as follows: 3) Blocks are removed from container and placed in situ; 4) Remains of blocks are collected and placed in container for disposal The possibilities for sediment contamination are negligible due to uses, method of application and properties of the product, except in the case of sewer baiting, when remains can get washed into sewage.	
air	Method of use is as follows: 5) Blocks are removed from container and placed in situ; 6) Remains of blocks are collected and placed in container for disposal The possibilities for air contamination are negligible due to uses, method of application and properties of the product. Product is of low v.p. at NTP, stable to heat, and comprises one large block which is not sprayed	
soil	Method of use is as follows: 7) Blocks are removed from container and placed in situ; 8) Remains of blocks are collected and placed in container for disposal The possibilities for soil contamination are negligible due to uses, method of application and properties of the product. Product is of low v.p. at NTP, stable to heat, and comprises one large block which is	

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	not sprayed on to soil. Product is used indoors, in sewers or in bait boxes with minimal direct soil contact.
Predicted concentration in the affected compartment(s)	
water	Local PEC's in aquatic compartments derived from the EUSES 2.0 model: Surface water during emission episode = 5.52 x 10^{-8} mg/l Annual average in surface water = 8.57x 10^{-9} mg/l
sediment	Local PEC's in aquatic compartments derived from the EUSES 2.0 model: Sediment during emission episode = 1.2x 10^{-3}mg/kg_{wwt}
air	Local PEC in air derived from the EUSES 2.0 model Annual average in air = 1.24 x 10^{-11} mg/m^3
soil	The predicted local soil PECs are derived from the total concentration in the soil (*Clocalsoil*) around the bait box taking into account both direct and disperse releases: *Clocal* $_{soil}$ = □*Clocal* $_{soil}$ + □□*Clocal* $_{soil\ ID}$ = 3.89E-03 mg/kg soil + 2.65E-03 mg/kg soil = 6.54E-03 mg/kg soil

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	2.3.2007 (STTV)/8.1.2008 (SYKE)
Materials and methods	
Conclusion	Point 2.10.2.2: The PECs calculated by RMS are presented in Document IIB of CA-report .
Reliability	0 (Not an experimental study)
Acceptability	Acceptable

Section A2.10 Annex Point IIA2.10	Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC
Remarks	Point 2.10.1.1: Production is beyond the scope of BPD. iii and iv: Data on exposure monitoring of operators is not available (see Table A2.10 and also related study summaries in section A6.12). Point 2.10.1.2: Results of a study in simulated use conditions (Chambers JG and Snowdon PJ 2004) are used to estimate the exposure of professionals and amateurs. RMS used the 75th percentiles of the data set. iii and iv: Exposure via drinking water or food is secondary in nature. Secondary exposure through food can not be totally excluded, because rodents may contaminate food and feeding stuffs to some extent with urine and faeces or by carrying baits to the surroundings. However, it can be considered to be limited due to the use pattern of the products. Under point iv, food should be referred to instead of drinking water. Secondary exposure through “transient mouthing of poison baits” is not mentioned. That scenario will be included in the risk assessment according to TNsG and User Guidance.
	COMMENTS FROM ...
Date	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A2.10: Workplace exposure / Inhalation exposure (use additional terminology from the TNsGs on Human exposure

Exposure scenario	Workplace operation	PPE	Year(s) of measurement	Number of measurements	Type of measurements	Exposure concentration
Production	Filling, cleaning	Full PPE inc respirator	None	None	None	None
Formulation	Opening concentrate container, or handling finished bait (0.005%)	Protective coverall, gloves,	None	None	None	None
Application MG./PT.	Placing baits, removing residues and decedents	Gloves,	None	None	None	None

It is to take in account that the active involved is an anticoagulant: it gains this property when chemical is completed coupling intermediate with 4-hydroxycoumarin. It is to be clear that only at this point the chemical begin an anticoagulant.
In addition the active is used only to prepare anticoagulant solutions at 2,5% or other percentage.

All staff, composed by 7 operators, is followed from 1975 by a doctor specialised in “hygiene and preventive medicine” and “work medicine”.

At beginning in 1975, staff was controlled each 3 months with haematochimical and urine examen.

After a period of ten years in 1985, since no kind of problems rise and all processes were well secured, medical surveillance was changed with:

- six-monthly medical visit made by the competent doctor,
- spyrometric annual control,
- six-monthly haematochimical and urine examen.

In 1995 another change was made: haematochimical and urine examen began annual.

All surveillance plan is made by the upper doctor who inspect also the production facilities with some surprise visit during working.

All upper results control are communicated to local authorities each year.

All documents can be showed on request.

No accidents occur from 1975 till today: this can demonstrate process safety and operator medical surveillance.