evaluate effects on carbon and nitrogen fixation. There was no significant effect on carbon fixation. However, there was more than a 25% reduction in nitrogen fixation after 91-days. Earthworms: Chlorfenapyr has been evaluated in a 14-day test and the LC_{50} was 23 mg a.s./kg soil. Testing has not been done with the metabolite, but it is expected to be less toxic than the active substance.

Plants: Screening studies have been performed in a wide variety of crop plants and weeds. Chlorfenapyr had minimal herbicidal activity, as one would expect for an insecticide. It should be noted that this test was not performed under GLPs. Additionally, chlorfenapyr is applied directly to plants without harm in plant protection products in many countries of the world.

Birds: Chlorfenapyr has been tested in acute oral studies with 2 species of birds. The 21-day acute oral LD_{50} values for the a.s. ranged from 10.8 to 34 mg/kg, indicating that the compound is highly toxic acutely to birds. Acute oral tests have also been conducted with the soil metabolite CL 312094 in 2 species of birds. The 14-day LD_{50} values ranged from 1687 to > 2400 mg a.s./kg bw, indicating low toxicity. Chlorfenapyr a.s. has been tested in 8day acute dietary studies in 2 species of birds. The LC_{50} values ranged from 8.6 to 132 ppm in the feed, placing the compound in the very highly toxic range. Chlorfenapyr a.s. has been also been tested in 20-week reproduction studies in 2 species of birds. The NOEC values ranged from 0.5 to 1.5 ppm in the feed.

Small Mammals: Acute testing has been performed with chlorfenapyr a.s. in the mouse. Acute Oral LD_{50} values were 45 and 75 mg a.s./kg bodyweight for males and females, respectively. These values place the compound in the highly toxic range. A 90-day dietary study has been performed in the beagle dog. The NOEC was 120 ppm in the diet. And, a chronic feeding and oncogenicity study has been performed with chlorfenapyr a.s. in the mouse. The NOEC was 20 ppm in the diet.

Honeybee: Chlorfenapyr a.s has been tested topically and orally in the honeybee. The 96-hr LD_{50} values by these routes were 1.0 and 0.33 µg/bee, respectively.

2.4 Non-compartment Specific Effects

AQUATIC COMPARTMENT

There is minimal potential for movement of chlorfenapyr through the aquatic food chain. First, and most importantly, residues in water or groundwater are predicted to be < 0.001 ppb for all exposure scenarios. As illustrated by the bioconcentration study submitted under Section A7.4.2 the minute amounts of chlorfenapyr in the aquatic compartment would be rapidly metabolized to the much less toxic AC 312,094. Total radioactivity (chlorfenapyr plus AC 312094) is rapidly excreted with a half-time of 4 days. The lack of exposure of water bodies means that concentrations of chlorfenapyr will be very low in fish, despite the overall BCF of 2080 – 2140. Fish-eating avian predators would not be exposed to chlorfenapyr.

TERRESTRIAL COMPARTMENT

There is also minimal potential for movement of chlorfenapyr through the terrestrial food chain. In the soil, the compound is extremely tightly bound, as illustrated by both the harsh conditions needed for the soil residue method (Section A4.2) and the low predicted potential for leaching (Section A7.2.3.2). The few earthworms exposed directly to the treated soil can be expected to contain the same levels of chlorfenapyr as the treated soil through which they burrow, but will not survive exposure to the treated soil. Worm-eating birds would therefore not be exposed. Because chlorfenapyr is tightly bound to soil and has limited systemic activity, it will not be taken up by plants.

Therefore, plants will not be a source exposure to higher levels of the food chain.

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3 MAMMALIAN TOXICOLOGY STUDIES

3.1 Conclusions

The dermal penetration rate was estimated from results of oral and dermal repeated-dose studies in rabbits. The dermal penetration rate derived from the ratios of NOAELs (110:5) is 5%, and the ratio of LOAELs (400:15) is 3.8%, indicating that the 5% rate is a conservative estimate of the dermal penetration rate.

For short- and intermediate-term oral exposure, the most sensitive species was the dog with a NOAEL in the 90-day study of 120 ppm (4.2 mg/kg b.w./day) based on the body weight effects at 200 ppm.

The NOAEL from the short-term dermal toxicity study in rabbits was 100 mg/kg b.w./day, based on decreases in erythrocyte counts and increases in serum cholesterol as well as increases in liver weights and an increased incidence of cytoplasmic vacuolation in the liver at 400 mg/kg b.w./day.

Results observed following long-term dietary administration of chlorfenapyr technical to rats, mice and dogs resulted in similar NOAELs for all three species, with the lowest NOAEL in rodents: 60 ppm in rats (2.9 and 3.6 mg/kg b.w./ day for males and females, respectively) and 20 ppm in mice (2.8 and 3.7 mg/kg b.w./ day for males and females, respectively). In rats 200 ppm caused decreases in mean body weight and body weight gain, decreases in albumin/globulin ratios, increases in mean total cholesterol and hepatocellular enlargement at 200 ppm for both genders. In mice 120 ppm caused reduced body weight gain and vacuolization of the white matter of the brain. The results were confirmed in a one-year neurotoxicity study in rats.

Chlorfenapyr has no genotoxic or carcinogenic properties and it did not show a potential for reproductive toxicity (developmental toxicity or fertility impairment). The most sensitive species was the dog with a short-term NOAEL in the 90-day study of 120 ppm (4.2 mg/kg b.w./day) based on the body weight effects at 200 ppm. The lowest NOAELs were detected in the chronic studies in rats and mice and similar NOAELs were detected in the one year dog study and the one-year neurotoxicity study in rats. The overall lowest chronic exposure NOAEL for systemic effects can be set at 3 mg/kg b.w./day.

The critical effect observed in the chronic studies and the one-year neurotoxicity study was vacuolation in the brain and spinal cord. This effect was not accompanied by direct, degenerative damage to myelin or axons and was not associated with any clinical behavioral effect. Moreover, the effect was fully reversible after termination of the exposure.

A safety factor of 100 is proposed. The short term and the chronic acceptable occupational exposure limit (AOEL) are 0.042 and 0.03 mg/kg b.w./day, respectively.

$$\text{Short term AOEL} = \frac{\text{lowest NOAEL}}{\text{Safety Factor}} = \frac{4.2\ \text{mg/ kg b.w./ day}}{100} = 0.042\ \text{mg/kg b.w./day}$$

$$\text{Chronic AOEL} = \frac{\text{lowest NOAEL}}{\text{Safety Factor}} = \frac{3\ \text{mg/kg b.w./day}}{100} = 0.03\ \text{mg/kg b.w./day}$$

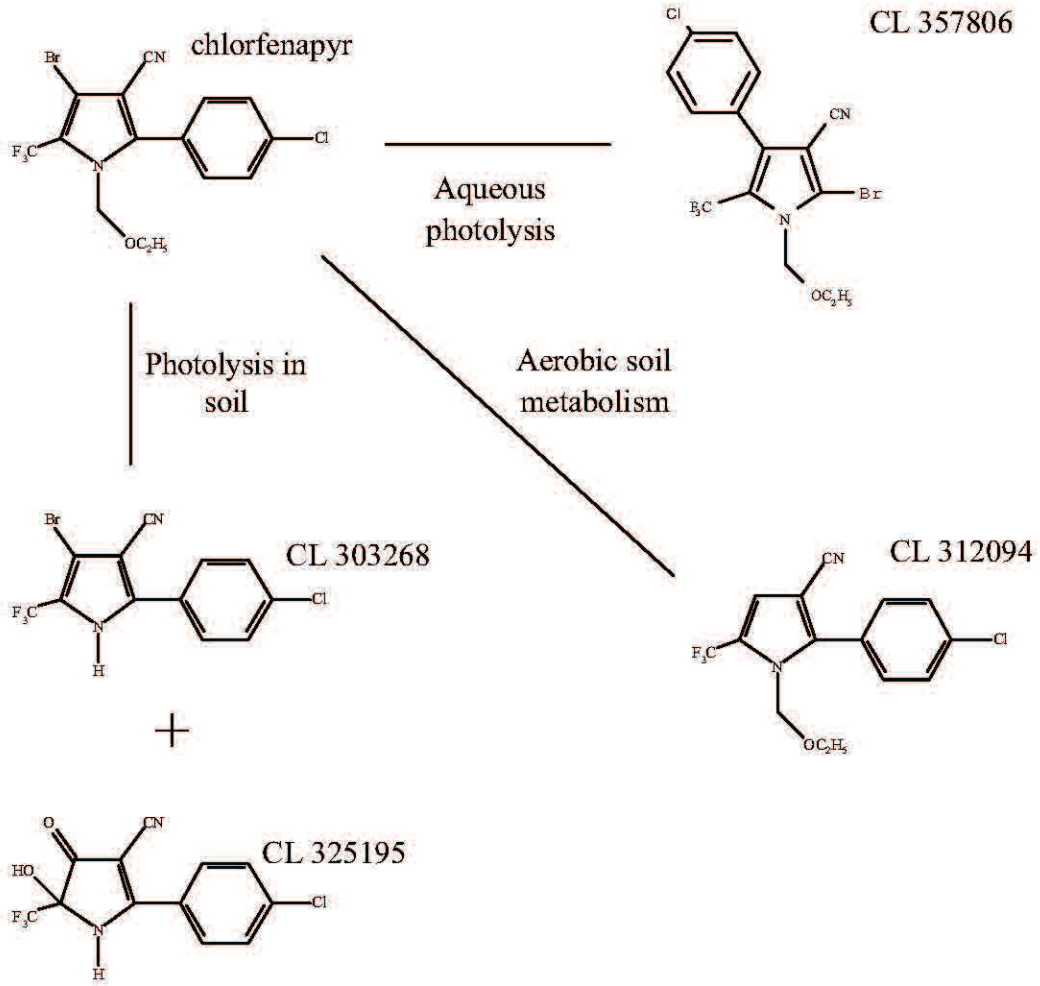
4 REFERENCES

[redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	20/05/2005
Materials and Methods	
Results and discussion	**Comments:** ***Environment:*** In **1.3**, the importance of microbes in the degradation of chlorfenapyr was not demonstrated in the soil degradations studies, since the relation between the microbial activity and degradation time was not preformed. However, in aquatic sediment systems, it was proved that the degradation of chlorfenapyr was much lower in sterile conditions; demonstrating microbes contribute to chlorfenapyr degradation. In **1.4**, some considerations about the chlorfenapyr behavior in aqueous phase should be included. In water sediment systems the chlorfenapyr moves rapidly from water to the sediment. In the loam water system the DT_{50} in water was not determinable due to low levels and noise. For sandy water system it was determinate DT_{50} of 97 and 114 days. Is important conclude that the affinity to the sediment phase is connected with the sediment texture. Once again, in **1.5**, previous considerations related with importance of microbial activity in soil degradation studies must be considered.
Conclusion	RMS agrees with applicant's version
Reliability	Not applicable
Acceptability	Acceptable
Remarks	No
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*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*
Results and discussion	*Discuss if deviating from view of rapporteur member state*

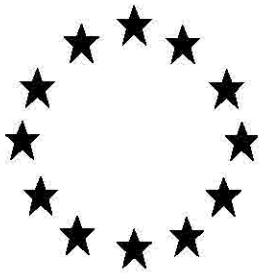
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Figure A7_6.1: Degradation pathway of chlorfenapyr.



Competent Authority Report

(according to Directive 98/8/EC)



CHLORFENAPYR

PT 8 (WOOD PRESERVATIVE BIOCIDE)

DOCUMENT III-A.8

Measures Necessary to Protect Man, Animals and the Environment

Rapporteur Member State: Portugal

October 2005

Section A8 Measures To Be Adopted To Protect Man, Animals And The Environment – Active Substance

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Section A8.1

Annex Point IIA, VIII.8.1

RECOMMENDED METHODS AND PRECAUTIONS CONCERNING HANDLING, USE, STORAGE, TRANSPORT OR FIRE

Personal protective equipment – X

Respiratory protection: self-contained breathing apparatus.
Hand protection: Suitable chemical resistant safety gloves (EN 374) also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): E.g. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), polyvinylchloride (0.7 mm) and other
Eye protection: Tightly fitting safety goggles (splash goggles) (EN 166)
Body protection: Body protection must be chosen depending on activity and possible exposure, e.g. apron, protection boots, chemical-protection suit (according to DIN-EN 465).
General safety and hygiene measures: Avoid contact with the skin, eyes and clothing. Wearing of closed work clothing is recommended. Keep separated from food-stuffs and feed-stocks. No eating, drinking, smoking or snuff-taking at the place of work. Hands and/or face should be washed before breaks and at the end of the shift.

Protection against fire and explosion –
No special precautions necessary. The substance is non-combustible and not explosive.

Storage –
Segregate from food and animal feeds. Protect against moisture. Keep away from heat. Protect from direct sunlight. Storage stability duration: 24 months.

Fire-fighting measures –
Suitable extinguishing media:
Water spray, dry extinguishing media, foam, carbon dioxide
Special protective equipment:
Wear self-contained breathing apparatus and chemical-protective clothing.
Further information:
Keep containers cool by spraying with water if exposed to fire. In case of fire and/or explosion do not breathe fumes. Collect contaminated extinguishing water separately, do not allow to reach sewage or effluent systems. Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

Section A8.2

Annex Point IIA, VIII.8.2

IN CASE OF FIRE, NATURE OF REACTION PRODUCTS, COMBUSTION GASES, ETC.

Specific hazards: carbon monoxide, carbon dioxide, hydrogen chloride, hydrogen fluoride, hydrogen bromide, nitrogen oxides

The substances/groups of substances mentioned can be released in case of fire.

Section A8 Measures To Be Adopted To Protect Man, Animals And The Environment – Active Substance

Section A8.3

Annex Point IIA, VIII.8.3

EMERGENCY MEASURES IN CASE OF AN ACCIDENT

General advice:
Avoid contact with the skin, eyes and clothing. Take off immediately all contaminated clothes. First aid personnel should pay attention to their own safety. If the patient is likely to become unconscious, place and transport in stable sideways position (recovery position). If difficulties occur: Obtain medical attention. Show container, label and/or safety data sheet to physician.

If inhaled: Keep patient calm, remove to fresh air, seek medical attention.

On skin contact: After contact with skin, wash immediately with plenty of water and soap.

On contact with eyes: Immediately wash affected eyes for at least 15 minutes under running water with eyelids held open, consult an eye specialist.

On ingestion: Immediate medical attention required.

Note to physician: Treatment: Treat according to symptoms (decontamination, vital functions), no known specific antidote.

Section A8 Measures To Be Adopted To Protect Man, Animals And The Environment – Active Substance

Section A8.4

Annex Point IIA, VIII.8.4

POSSIBILITY OF DESTRUCTION OR DECONTAMINATION FOLLOWING RELEASE IN OR ON THE FOLLOWING: (A) AIR (B) WATER, INCLUDING DRINKING WATER (C) SOIL

There should be no release of the active substance prior to its intended end-use into air, water or soil. In case of accidental release:

(a) Decontamination of air: Air contamination is not expected because the product is non-volatile.

(b) Decontamination of potable water:
In case of contamination of subsurface or surface water:
1. Immediately contain the source of contamination.
2. Do not allow people or pets to contact or otherwise use the contaminated water.
3. Notify the appropriate authorities. If the water body concerned is moving, stream or river, then the authorities down stream should be notified of the contamination. In these instances the movement of the water body and consequent dilution of chlorfenapyr, the active ingredient in MYTHIC, will aid dissipation.
4. Wear appropriate personal protective equipment.
5. Water samples should be taken from the wellhead or other discharge point and analyzed to determine the presence and level of contamination. Decontamination procedures should be implemented if the concentration of chlorfenapyr in the water is greater than 0.18 mg/L. This is the potable water Health Advisory Level (HAL) for chlorfenapyr that BASF has determined is not expected to cause any adverse health effects.
6. Water with chlorfenapyr levels above 0.18 mg/L should be passed over a suitable filter until the decontamination procedure is completed. BASF recommends using Powdered Activated Carbon CPH from Calgon following Calgon's standard carbon isotherm protocol (Application Bulletin AB-002-12/93).
7. Decontamination is complete when levels of chlorfenapyr are below its HAL of 0.18 mg/L.

(c) Decontamination of soil:
In case of spills of the active substance to the soil surface that are not intended for treatment.
- Wear appropriate personal protective equipment.
- For small amounts: Sweep/shovel up. For large amounts: Sweep/shovel up. Avoid raising dust. Collect waste in suitable containers, which can be labeled and sealed.
- Remove the contaminated soil and dispose of according to local regulations.

Section A8.5

Annex Point IIA, VIII.8.5

PROCEDURES FOR WASTE MANAGEMENT OF THE ACTIVE SUBSTANCE FOR INDUSTRY OR PROFESSIONAL USERS

Production Facility: Waste with active ingredients are collected separately and sent to a treatment plant for incineration by an approved center. A BSDI is sent back to BASF to prove the destruction has been done correctly.

Section A8 Measures To Be Adopted To Protect Man, Animals And The Environment – Active Substance

Section A8.5.1

Annex Point IIA, VIII.8.5.1

POSSIBILITY OF RE-USE OR RECYCLING

All chlorfenapyr technical within specification is used for formulating into end-use products. If any material were produced that was out of specification, BASF would make every effort to rework the material so that it could be used. All waste from the formulation process is incinerated.

Section A8.5.2

Annex Point IIA, VIII.8.5.2

POSSIBILITY OF NEUTRALIZATION OF EFFECTS

Residues of chlorfenapyr from non-porous surfaces with a detergent solution. BASF recommends either liquid Tide (0.25% concentration of product in water), or liquid Lysol (6.25% concentration of product in water).

Residues of chlorfenapyr from porous surfaces can be mostly removed with a detergent solution. Any remaining residue can be neutralized with a solution containing at least 1% bleach.

Section A8.5.3

Annex Point IIA, VIII.8.5.3

CONDITIONS FOR CONTROLLED DISCHARGE INCLUDING LECHATE QUALITIES ON DISPOSAL

BASF would not utilize a controlled discharge. Incineration would be used.

Section A8.5.4

Annex Point IIA, VIII.8.5.4

CONDITIONS FOR CONTROLLED INCINERATION

The technical can be incinerated. The material would be dissolved in a suitable solvent and fed to the plant incinerator located in Missouri, USA. X

The active substance is manufactured in the U.S. [redacted]. Incineration destruction tests were conducted in accordance with U.S. Environmental Protection Agency (EPA), Missouri Department of Natural Resources (MDNR) and the Federal Resource Conservation Recovery Act (RCRA) regulations under the supervision of MNDR. A minimum destruction of 99.99% was demonstrated for the stack gases and 99.9% for the scrubber effluent water. The incineration is performed in Zink incinerators at 830C with a minimum of one-second residence time in the thermal oxidizer. For 2003 the [redacted] plant averaged less than 0.05 lbs/day for all pesticide active ingredients in the treated plant effluents after incineration.

Section A8.6

Annex Point IIA, VIII.8.6

OBSERVATIONS ON UNDESIRABLE OR UNINTENDED SIDE-EFFECTS, FOR EXAMPLE, ON BENEFICIAL AND OTHER NON-TARGET ORGANISMS

No observations of undesirable or unintended side effects from the manufacture of the active substance or biocidal product have been reported to BASF.

Table A8.6 contains reports made to BASF of potential undesirable or unintended side effects from products containing the active substance.

Section A8 Measures To Be Adopted To Protect Man, Animals And The Environment – Active Substance

Section A8.7

Annex Point IIIA, VIII..1

IDENTIFICATION OF ANY SUBSTANCES FALLING WITHIN THE SCOPE OF LIST I OR LIST II OF THE ANNEX TO DIRECTIVE 80/68/EEC ON THE PROTECTION OF GROUND WATER AGAINST POLLUTION CAUSED BY CERTAIN DANGEROUS SUBSTANCES.

The active substance is not on list I of the annex to directive 80/68/EEC.

The active substance falls within the scope of list II because all substances not specifically identified on list I but used as a biocide are by default included on list II.

Section A8 Measures To Be Adopted To Protect Man, Animals And The Environment – Active Substance

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	
Comments on applicant's data	**Section A8.1** **Transport information**

Land transport

ADR	:	Class	6.1
		Packaging group	III
		UN-number	2588
		Designation of goods	PESTICIDE, SOLID, TOXIC, N.O.S. (Contains: CHLORFENAPYR)
RID	:	Class	6.1
		Packaging group	III
		UN-number	2588
		Designation of goods	PESTICIDE, SOLID, TOXIC, N.O.S. (Contains: CHLORFENAPYR)

Inland waterway transport

ADNR	:	Class	6.1
		Item/Letter	73c)
		Packaging group	III
		UN-number	2588
		Designation of goods	PESTICIDE, SOLID, TOXIC, N.O.S. (Contains: CHLORFENAPYR)

Sea transport

IMDG/GGVSee	:	Class	6.1
		Packaging group	III
		UN-number	2588
		Marine pollutant	YES
		Exact technical name	PESTICIDE, SOLID, TOXIC, N.O.S. (contains CHLORFENAPYR)

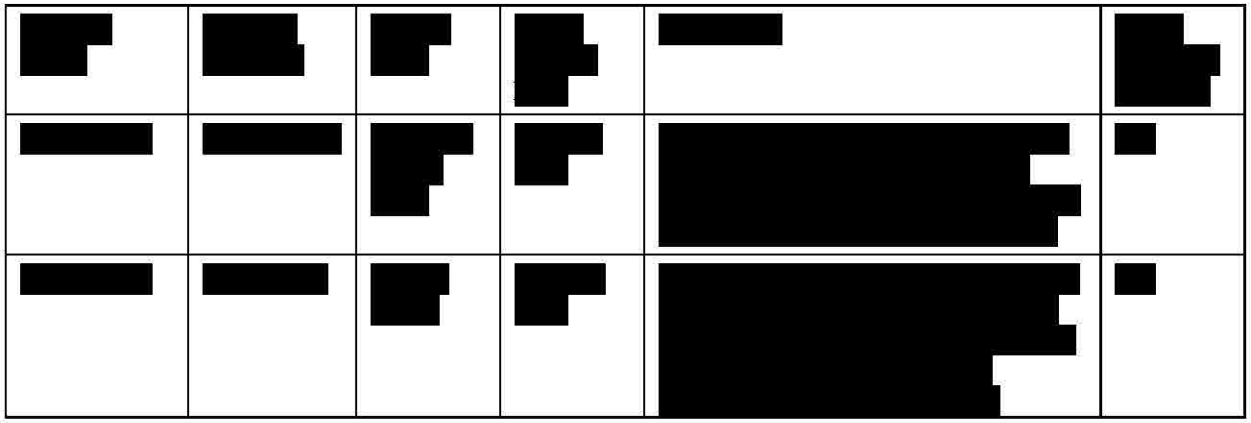
Section A8 Measures To Be Adopted To Protect Man, Animals And The Environment – Active Substance

	Air transport		
	ICAO/IATA :	Class	6.1
		Packaging group	III
		UN-number	2588
		Exact technical name	PESTICIDE, SOLID, TOXIC, N.O.S. (contains CHLORFENAPYR)
	Section A8.5.4 As the halogen content is less than 60% the pyrolytic behaviour is not required.		
Conclusion	A material safety data sheet for chorphenapyr was provided. All points were fully addressed.		
Acceptability	Information acceptable.		
Remarks			

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Comments on applicant's data	*For additional comments referring to the (sub)heading numbers. Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

A8.6
US EPA requires the submission of information concerning adverse effects as required by FIFRA §6(a)(2). Information is required to be submitted when a registrant becomes aware of an allegation of exposure and an allegation of effect. As is nearly always the case with incident reports, it is extremely difficult to conclusively determine the cause of the effect(s) reported. These reports should not be interpreted to mean that BASF believes that the effects reported are necessarily related to the exposure alleged.

Table A8.6



[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

Competent Authority Report

(according to Directive 98/8/EC)

CHLORFENAPYR

PT 8 (WOOD PRESERVATIVE BIOCIDE)

DOCUMENT III-A.9

Classification and Labelling

Rapporteur Member State: Portugal

October 2005

Section A9(01) Classification, Packaging and Labeling

Annex Point
IIA, IX

9.1

PROPOSED CLASSIFICATION

The following classification of danger and risk phrases for chlorfenayr were proposed by ECB Ispra, 25-27 April 2001:

Classification:	T; R23 : Xn; R22 : N; R50/53	
Class of danger:	Toxic, Dangerous for the environment, Harmful	X[1]
R phrases:	R22, R23, R50/53	
S phrases :	S1, S2, S13, S20/21, S36/37, S45, S60, S61	X[2]

Current labelling for the technical a.s.:

Classification:	T, N	
Class of danger:	Toxic, Dangerous for the environment	
R phrases:	R22, R23, R50/53	
S phrases :	S1, S2, S13, S20/21, S36/37, S45, S60, S61	X[3]

9.2

PROPOSED CONTAINER LABEL

See A9(02).doc for the proposed chlorfenapy technical shipping label text. X

9.3

PROPOSED MATERIAL SAFETY DATA SHEET

See A9(03).doc for the chlorfenapyr material safety data sheet.

Section A9(01) Classification, Packaging and Labeling

Annex Point
IIA, IX

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	June 2005
Comments on applicant's data	X[1]: Harmful doesn't belong to the class of danger X[2]: S20/21 is not proposed by ECB Ispra X[3]: the same as above (S20/21 is not proposed by ECB Ispra) RMS agrees with ECB classification, but proposes to add the R-phrase R48/22 due to histopathological effects observed in the neurotoxicity study, that were confirmed in other toxicological studies (see Document III-A6.9/02, III-A6.18.9) RMS proposes also to include the S-phrases S4 and S63 due to the classification with T; R23. **9.2 Proposed container Label** The active substance content must be the minimum specified 94 %w/w.
Conclusion	RMS proposal is the following:

Classification	T; N
Class of danger	Toxic, Dangerous for the environment,
R phrases	R22, R23, R48/22, R50/53
S phrases	S1/2, S4, S13, S36/37, S38, S45, S60, S61, S63

Acceptability	Information acceptable.
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Comments on applicant's data	*For additional comments referring to the (sub)heading numbers. Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Text of Proposed Chlorfenapyr Technical Label

Product Name:	**CHLORFENAPYR TECHNICAL**
UN Classification:	**UN 2588**
Chemical Description:	**PESTICIDE, SOLID, TOXIC, N.O.S. (Contains: CHLORFENAPYR), MARINE POLLUTANT**
Package Group:	(PG III) WGK 3
Active Ingredient:	**Chlorfenapyr 97.1%**
Symbol (T):	Toxic
Symbol (N):	Dangerous for the Environment
R/S Phrases:	R: 22-23-50/53 S: 1-2-13-20/21-36/37-45-60-61
R Phrase (22):	**Harmful if swallowed**.
R Phrase (23):	**Toxic by inhalation.**
R Phrase (50/53):	**Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.**
S-Phrase (1)	Keep locked up.
S-Phrase (2)	Keep out of the reach of children.
S-Phrase (13):	Keep away from food, drink and animal feeding stuffs.
S-Phrase (20/21):	When using, do not eat, drink or smoke.
S-Phrase (36/37):	Wear suitable protective clothing and gloves.
S-Phrase (45):	In case of accident or if you feel unwell, seek medical advice immediately.
S-Phrase (60):	This material and its container must be disposed of as hazardous waste.
S-Phrase (61):	Avoid release to the environment. Refer to special instructions/safety data sheets.
Other symbol (5301):	Protect from heat
Net Content:	49.9 kg
EU Label Address:	BASF Aktiengesellschaft 67056 Ludwigshafen Germany Tel. +49-(0)621-60-43333