Section A7.4.2 Bio-concentration in aquatic organisms
Annex Point IIA, VII.7.5 Carp, *Cyprinus carpio*

Results and discussion	Adopt applicant's version.
Conclusion	Adopt applicant's version.
Reliability	1
Acceptability	acceptable
Remarks	The study is considered to be fully reliable and hence can be used for risk assessment purposes.
	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*
Reliability	*Discuss if deviating from view of rapporteur member state*
Findings	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table 7.4.2-1 Measured concentrations in the water during the uptake phase.

Nominal concentration (µg/L)	Measured concentration (µg/L)							
	day 0	day 4	day 6	day 12	day 15	day 22	day 28	Average (S.D.)
0.05	0.0500	0.0506	0.0497	0.0466	0.0478	0.0466	0.0493	0.0484 (0.00168)
0.005	0.00488	0.00501	0.00471	0.00465	0.00483	0.00474	0.00483	0.00480 (0.000125)

Table 7.4.2-2 Measured concentrations in the tissue during the uptake phase.

Nominal concentration (µg/L)	Measured concentration (µg/g)						
	day 4	day 6	day 12	day 15	day 22	day 28	Average (S.D.)
0.05	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
0.005	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.

n.d. = not detected (Limit of detection = 0.15 ng/g)

91/414/EEC Annex	**II**	**Bioaccumulation in Fish**
98/8/EC Annex	**IIA7.5**	
PPPD Point addressed	**8.2.3**	
BPD Point addressed	**A7.4.2**	

For Official Use Only

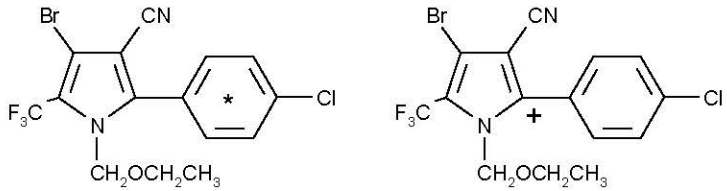
1.1	**Title**	CL 303,630: Uptake, Depuration, Bioconcentration and Metabolism of Carbon-14 CL 303,630 in Bluegill Sunfish (*Lepomis macrochirus*) Under Flow-Through Test Conditions [redacted]
1.2	**Report Number**	[redacted]
1.3	**Lab Report No.**	[redacted]
1.4	**Cross Reference**	8.2.3
1.5	**Authors**	[redacted]
1.6	**Date of Report**	November 3, 1994
1.7	**Published**	No
1.8	**Data Protection and Owner**	Yes; BASF
1.9	**Criteria for Data Protection**	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its Approval.
2.1	**Testing Facility**	[redacted]
2.2	**Dates of Experimental Work**	October 9, 1991 - October 31, 1992

3 Objectives

To determine the bioaccumulation potential and metabolic fate of CL 303,630 in a fresh water fish (bluegill sunfish), to quantitate and identify the metabolites of CL 303,630 in the edible and non-edible portions of the fish and to quantitate and identify CL 303,630-derived radioactivity in the aquaria water after independent exposure to [*Phenyl-(U)*-^{14}C] and [*2-Pyrrole*-^{14}C] labeled CL 303,630 each at a nominal concentration of 1 µg/L (1 ppb).

4.1 Test Substance

Pyrrole-3-carbonitrile, 4-bromo-2-(p-chlorophenyl)-1-(ethoxy-methyl)-5-(trifluoromethyl)-



(*) denotes [*Phenyl (U)*-^{14}C] label
(+) denotes [*2-Pyrrole*-^{14}C] label

[*Phenyl (U)*-^{14}C] CL 303,630
Lot Number AC 8019-023; radiopurity, 98.6% (TLC); chemical purity, 97.3% (HPLC); specific activity, 53.39 µCi/mg;

[*2-Pyrrole*-^{14}C] CL 303,630
Lot Number AC 8019-015; radiopurity, 98.0% (TLC); chemical purity 97.1% (HPLC); specific activity 56.63 µCi/mg;

Nonradiolabeled CL 303,630
Lot Number AC 6937-118-1, chemical purity, 98.8% (GC)

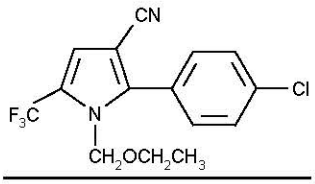
4.2	**Specification**	^{14}C-CL 303,630 (Lot Numbers AC 8019-023 and AC 8019-015) were each mixed with acetone in volumetric flasks to yield [*Phenyl (U)*-^{14}C] CL 303,630 and [2-*Pyrrole*-^{14}C] CL 303,630 diluter stock solutions whose concentrations were 14.2 mg/L and 15.6 mg/L, respectively. The diluter systems were calibrated by volumetric measurements of the mixing cell volumes. A 0.1 mL aliquot of [*Phenyl (U)*-^{14}C] CL 303,630 diluter stock solution (14.2 mg/L) was delivered to 14,060 mL of dilution water in the toxicant mixing cell to yield a nominal exposure concentration of 1.0 µg/L. A 0.1 mL aliquot of [2-*Pyrrole*-^{14}C] CL 303,630 diluter stock solution (15.6 mg/L) was delivered to 15,080 mL of dilution water in the toxicant mixing cell to yield a nominal exposure concentration of 1.0 µg/L. The 1.0 µg/L concentration of test substance used in this study is approximately 1/10 the CL 303,630 LD_{50} in bluegill sunfish as determined in a 96-hour flow through test. During the 33-day exposure period the 70 liter volume of water in each of the testing aquaria containing ^{14}C-CL 303,630 was replaced 6.4-6.9 times in each 24 hour period *via* the flow through system.
4.3	**Storage Stability**	Not applicable
4.4	**Stability in Vehicle**	Radioactivity in the diluter stock solutions was characterized during the exposure phase of the study on days 0, 14 and 33. [*Phenyl (U)*-^{14}C] CL 303,630 and [2-*Pyrrole*-^{14}C] CL 303,630 accounted for an average of 99% of the total activity at each time point indicating that the test substances were stable over the term of the study.
4.5	**Homogeneity in Vehicle**	Not Applicable
4.6	**Validity**	Not applicable
5	**Vehicle/Solvent**	The diluter stock solutions of test substance were prepared in acetone. The nominal concentrations of test substance in each aquaria was 1 µg/L. Each 70 liter test volume contained 100 µl of acetone.
6	**Physical Form**	Liquid
7.1	**Test Method**	U.S. EPA Pesticide Assessment Guidelines: Environmental Chemistry (Subpart N); Guideline No. 165-4 (1982)
7.2	**Justification**	Required for U.S. registration under FIFRA
7.3	**Copy of Method**	Description contained in report
8	**Choice of Method**	Not applicable

9	**Deviations**	Not applicable	
10.1	**Certified Laboratory**	Not applicable	
10.2	**Certifying Authority**	Not applicable	
10.3	**GLP**	Study was conducted in accordance with EPA Good Laboratory Practices, 40 CFR Part 160	
10.4	**Justification**	Not applicable	
11.1	**GEP**	Not applicable	
11.2	**Type of Facility**	Not applicable	
11.3	**Justification**	Not Applicable	
12	**Test System**	Species	Bluegill Sunfish (*Lepomis macrochirus*)- Lot No. 1691
		Number	600
		Source	[redacted]
		Age	< 1 year at time of testing
		Length	Initial mean standard length was 57 ± 5.9 mm; 72 ± 7.2 mm after the 33-day exposure period.
		Weight	Initial mean weight was 5.96 ± 2.21 g; 14.42 ± 4.43 g after the 33-day exposure period.
		Water Quality	Source, well water; pH, 7.7-8.2; Aquaria water temperature, 21°C; Dissolved oxygen concentration, 6.1-8.6 mg/L (71 and 101% saturation at 21°C)

		Treatment	A flow-through proportional diluter system was used for the intermittent introduction of radiolabeled test material and dilution water into the test chambers. This system maintained a mean measured water concentration of 0.84 ± 0.13 µg/L [*Phenyl (U)*-^{14}C] CL 303,630 and 0.96 ± 0.19 µg/L [*2-Pyrrole*-^{14}C] CL 303,630 during the 33-day exposure period.
13	**Findings**	A dynamic 54-day study was conducted to evaluate the bioconcentration of CL 303,630 by bluegill sunfish (*Lepomis macrochirus*). A flow-through proportional diluter system was used, which maintained a mean measured water concentration of 0.84 ± 0.13 µg/L of [*Phenyl(U)* ^{14}C] CL 303,630 and 0.96 ±0.19 µg/L of [*2-Pyrrole* ^{14}C] CL 303,630 for a 33 day exposure period. The test substance was withdrawn and a 14-day depuration period followed. Total radioactive residue (TRR) was determined in whole fish, fillet and aquaria water on days 0, 1, 3, 7, 14, 21, 28 and 33 of the exposure phase and days 1, 3, 7, 10, 14 and 21 of the depuration phase. Metabolite identification in whole fish, fillet and viscera was conducted on fish sampled from the [*Phenyl(U)* ^{14}C] and [*2-Pyrrole* ^{14}C] CL 303,630 treatments on days 21 and 33. In addition, the radioactivity in the water was also characterized by HPLC at each sampling interval during the exposure phase. A steady-state concentration of radioactivity in fish was observed after 21-days of exposure to CL 303,630. The maximum total radioactive residues (TRR) in whole fish, fillet and viscera were in the ranges 2000 to 2200, 880 to 980, and 2900 to 3700 ppb, respectively. The residue concentrations were <10% of the steady-state concentrations 21 days after the start of depuration.	

More than 95% of the CL 303,630-derived radioactivity in the whole fish, fillet, and viscera was extractable. HPLC/^{14}C analysis revealed that the radioprofiles of the extracted residues from whole fish, viscera and fillet derived from the [*Phenyl (U)* ^{14}C] and [*2-Pyrrole* ^{14}C] CL 303,630 exposures were qualitatively similar indicating that there was no fragmentation of the parent molecule. CL 312,094 (shown below) was the only major component of the residue in fish accounting for 89 to 95% (585 – 3352 µg/Kg) of the total radioactive residue at steady-state. The oral LD50 of this non-toxic metabolite in albino rats is >5000 mg/kg. CL 303,630 accounted for < 3% of the TRR (12-85 µg/Kg).

C18 solid phase extraction of the aquaria water samples followed by HPLC/^{14}C analysis showed that >95% of the extracted radioactivity was due to CL 303,630 and CL 312,094. Between days 1 and 33 of the uptake period, the percentage of extracted radioactivity due to CL 303,630 decreased from an average of 73% on day 1 to an average of 53% by day 7, then remained fairly constant through day 33 uptake. The percentages of CL 312,094 increased from an average of 27% on day 1 to any average of 40% on day 33.



CL 312,094 [Pyrrole-3-carbonitrile, 2-(p-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-]

		The bioconcentration factors (BCF) calculated on the basis of total CL 303,630-derived radioactivity in whole fish and aquarium waters were 2084 to 2136 during the exposure phase. The uptake rate constant (K_1) was 356 to 412 µg/Kg fish/µg/L water/day and the depuration rate constant (K_2) was 0.171 day^{-1}. The time to reach 90% of Steady State was 12 to 14 days. The $t_{1/2}$ for clearance of the total radioactive residue during the depuration phase was 3 to 4 days. The time for 90% depuration of the total radioactive residues was 14 days Since CL 312,094, the desbromo analog of CL 303,630, was also a major component in the aquaria water accounting for up to 40% of the total radioactivity, the estimated BCF factor for CL 303,630 was significantly less (83 to 114) in whole fish when calculated on the basis of the actual CL 303,630 concentration at day 21 and day 33 in whole fish (36 and 41 µg/Kg for phenyl-label, 28 and 35 µg/Kg for pyrrole-label) and water (0.35 and 0.36 µg/Kg for phenyl-label, 0.32 and 0.42 µg/Kg for pyrrole-label, respectively). Thus, in bluegill sunfish, the principal metabolic pathway is reductive debromination to yield CL 312,094, which is the only major component found in fish tissue and aquaria water.
14	**Statistics**	Mean and standard deviation were used for in calculation of total radioactive residues; a BIOFAC computer modeling program was used to determine the uptake and depuration rate constants and the calculation of the bioconcentration factors (BCF) in whole, fish, fillet and viscera.
15	**References**	No publications cited in this summary
16	**Unpublished Data**	[redacted] "Acute Toxicity of AC 303,630 to Bluegill Sunfish (*Lepomis macrochirus*) under Flow-Through Test Conditions" [redacted]
17	**Conclusion**	BAS 306I did accumulate in the tissues of the bluegill sunfish, but was rapidly metabolized to CL 312094 and depurated.
18	**Reliability**	Reliability Indicator of 1.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*Give date of action*
Materials and Methods	*State if the applicant's version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.*
Results and discussion	*Adopt applicant's version or include revised version. If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers*
Conclusion	*Adopt applicant's version or include revised version*
Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator*
Acceptability	acceptable / not acceptable *(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliability indicator. Discuss the relevance of deficiencies and indicate if repeat is necessary.)*
Remarks	
	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*
Reliability	*Discuss if deviating from view of rapporteur member state*
Findings	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

91/414/EEC Annex	**II**	**Fish Juvenile Growth Test 28 Days to Rainbow Trout**
98/8/EC Annex	**IIIA, XIII 2.1**	
PPPD Point addressed	**8.2.2.2**	
BPD Point addressed	**7.4.3.1**	

For Official Use Only

1.1	**Title**	Toxicity of AC 303,630 to the Rainbow Trout (Oncorhynchus mykiss) After 28 Days of Exposure Under Flow-Through Test Conditions [redacted]
1.2	**Report Number**	[redacted]
1.3	**Lab Report No.**	[redacted]
1.4	**Cross Reference**	8.2.2.2
1.5	**Authors**	[redacted]
1.6	**Date of Report**	August 5, 1994
1.7	**Published**	No.
1.8	**Data Protection and Owner**	Yes; BASF
1.9	**Criteria for Data Protection**	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its Approval
2.1	**Testing Facility**	[redacted]
2.2	**Dates of Experimental Work**	September 10, 1993 - October 8, 1993
3	**Objectives**	To determine the threshold level of lethal effect (TLLE), the threshold level of observed effect (TLOE) and the no-observed-effect concentration (NOEC) of AC 303,630 to the rainbow trout after 28 days of exposure under flow-through test conditions.
4.1	**Test Substance**	AC 303,630
4.2	**Specification**	Lot Number AC7504-59A, 94.5% pure.
4.3	**Storage Stability**	Stable during the course of the study.
4.4	**Stability in Vehicle**	Based on weekly measurements of the stock solution during the test, the test substance was stable in the vehicle.

4.5	**Homogeneity in Vehicle**	Based on the consistent measured concentrations of AC 303,630 in the test solutions during the test, homogeneity in the vehicle was maintained.
4.6	**Validity**	Not applicable.
5	**Vehicle/Solvent**	Dimethylformamide.
6	**Physical Form**	Powder.
7.1	**Test Method**	OECD Method Number 204.
7.2	**Justification**	Not applicable.
7.3	**Copy of Method**	A copy is included in the report.
8	**Choice of Method**	Not applicable.
9	**Deviations**	None.
10.1	**Certified Laboratory**	Not applicable.
10.2	**Certifying Authority**	Not applicable.
10.3	**GLP**	The study was conducted in accordance with Good Laboratory Practice Standards as set forth by the Organization for Economic Cooperation and Development (OECD) ISBN 92-64-12367-9 and the U.S. EPA 40 CFR Part 160.
10.4	**Justification**	Not applicable.
11.1	**GEP**	Not applicable.
11.2	**Type of Facility**	Not applicable.
11.3	**Justification**	Not applicable.
12	**Test System**	
	Animal Species:	Rainbow Trout (Oncorhynchus mykiss)
	Source:	[redacted]

Number of Animals:	Twenty per treatment.
Number of Treatments:	Five treatments, a no-treatment control and a vehicle control.
Test Levels:	0 (no-treatment control), 0 (vehicle control), 0.86, 1.74, 3.86, 8.91, and 20 ug/L (measured water concentrations)
Administration:	The test solutions were prepared and delivered to the test vessels by a proportional diluter system. The test animals were exposed to the test substance in the water.
Duration:	28 Days.
General Observations:	The number of mortalities in each treatment was recorded daily. At test termination, the wet weights and standard lengths of all live fish were determined.

13	**Findings**	
	Test concentrations:	Mean measured concentrations of 0.86, 1.74, 3.86, 8.91, and 18.0 ug/L for 28 days.
	Mortalities:	No-treatment control - 0 of 20 (0%) Vehicle control - 0 of 20 (0%) 0.86 ug/L - 0 of 20 (0%) 1.74 ug/L - 1 of 20 (5%) 3.86 ug/L - 4 of 20 (20%) 8.91 ug/L - 20 of 20 (100%) 18.0 ug/L - 20 of 20 (100%)
	Mean Standard Lengths:	No-treatment control - 4.1 cm Vehicle control - 4.2 cm 0.86 ug/L - 4.1 cm 1.74 ug/L - 4.1 cm 3.86 ug/L - 4.2 cm (all fish were dead at 8.91 and 18.0 ug/L)
	Mean Wet Weights:	No-treatment control - 1.13 g Vehicle control - 1.17 g 0.86 ug/L - 1.05 g 1.74 ug/L - 1.04 g 3.86 ug/L - 1.06 g (all fish were dead at 8.91 and 18.0 ug/L)
	Results:	The 28-day LC50 of AC 303,630 to the rainbow trout was 4.58 ug/L and the 95% confidence limits were 3.73 and 5.63 ug/L. The TLLE was 1.74 ug/L based on 5% more mortality in this treatment in comparison to the controls. In comparison to the pooled controls, there were no statistically significant differences in standard lengths or wet weights in all treatment groups $\leq$ 3.86 ug/L. Therefore, the TLOE was > 3.86 ug/L. Therefore, the NOEC in this study (based on mortality) was 0.86 ug/L.
14	**Statistics**	The 28-day LC50 and 95% confidence limits were determined by the Probit method. Effects on wet weight and standard lengths were evaluated using analysis of variance procedures.
15	**References**	None.
16	**Unpublished Data**	None used in the study.

17	**Conclusion**	The compound was very highly toxic to the rainbow trout. This result is consistent with findings from other fish studies. Dissolved oxygen generally remained at greater than 60% of saturation in all treatments and the controls through the first 14 days of the test. From test day 17 through 28, dissolved oxygen was generally in the range of 50% to 60% of saturation in the treatment vessels. Mortality of the control and solvent control fish was less than 10% throughout the test. The concentrations of the test substance during the test remained at least 80% of the initial measured concentrations. Temperature range per day was generally within a range of 2° C. Mean temperature per day generally did not vary by more than 1° C between consecutive days. Temperatures were in the acceptable range for rainbow trout. The minor excursions from optimal temperature and dissolved oxygen control are not considered to have adversely affected the results of the study.
18	**Reliability**	Reliability indicator of 1.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State
Date	*Give date of action*
Materials and Methods	*State if the applicant's version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.*
Results and discussion	*Adopt applicant's version or include revised version. If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers*
Conclusion	*Adopt applicant's version or include revised version*
Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator*
Acceptability	acceptable / non acceptable *(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliability indicator; if unacceptable, give reasons for unacceptability of study; discuss the relevance of the deficiencies. Indicate if repeat is necessary)*
Remarks	
	Comments from ... *(SPECIFY)*
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	

Section A8.1 Annex Point IIA,VIII.8.1	Recommended methods and precautions concerning handling, use, storage, transport or fire	Official use only

Handling and storage

Handling:

Good standards of hygiene should be maintained at all times.
Smoking, eating and drinking is prohibited in the working area.
Do not take internally.
Avoid contact with skin, eyes and clothing.
Upon contact with skin or eyes, wash off with water and seek medical advice.
Avoid breathing dust, mist or vapour.

Information about fire and explosion protection:

As with other combustible materials, avoid storage and handling conditions which lead to formation of dust clouds. Dust clouds are susceptible to ignition by electrical (static) discharge. Static charges can accumulate during shipping, unloading, pouring or conveying. To avoid fire or explosions, ground and bond container, receiving equipment (and ground personnel) before transferring material.

Storage:

Shelf Life: 1 year when stored unopened in original container in a dry place at room temperature.
Do not use or store near open flames.
Store in a cool location.
Store away from oxidizing agents.
Protect from heat and direct sunlight.
Do not store at high temperatures

Exposure controls/Personal protection

Respiratory protection:

In case of heavy exposure, wear a gas mask.

Protection of hands:

Impervious gloves.

Eye protection:

Chemical workers goggles.

Body protection:

A full suit may be required if exposure to large areas of the body is possible.
Apron
Boots

Section A8.1 Annex Point IIA,VIII.8.1	Recommended methods and precautions concerning handling, use, storage, transport or fire

Additional Information:

Eye fountain and washing facilities at work area.

Transport information

ADR/RID:

class: 6.1 Toxic substances.
UN-Number: 2588
Packaging group: II
Hazard label 6.1
Description of goods: 2588 PESTICIDE, SOLID, TOXIC, N.O.S. (tralopyril)

Maritime transport IMDG:

IMDG Class: 6.1
UN Number: 2588
Label 6.1
Packaging group: II
Proper shipping name: 2588 PESTICIDE, SOLID, TOXIC, N.O.S. Marine Pollutant (tralopyril)

Air transport ICAO-TI and IATA-DGR:

ICAO/IATA Class: 6.1
UN/ID Number: 2588
Label 6.1
Packaging group: II
Proper shipping name: 2588 PESTICIDE, SOLID, TOXIC, N.O.S. (tralopyril)

Fire-fighting measures

Suitable extinguishing agents:

Water, foam, dry chemical or carbon dioxide. Avoid breathing dusts, vapours and fumes from burning materials.

Protective equipment:

Wear self-contained positive pressure breathing apparatus and full fire fighting protective clothing.

Additional information:

Take note of surrounding materials.
Cool endangered receptacles with water spray.
In case of fire use normal fire fighting equipment.

Materials to be avoided:

Stable in presence of copper and iron.

Section A8.1 Annex Point IIA,VIII.8.1	Recommended methods and precautions concerning handling, use, storage, transport or fire
	Dangerous decomposition products: Potential decomposition products include HF, HBr, HCl and oxides of nitrogen and carbon. (Reference: Anonymous, 2005)
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	15/03/2010
Evaluation of applicant's justification	The recommended methods and precautions concerning handling, use, storage, transport or fire appear comprehensive and acceptable.
Conclusion	The applicant's justification is acceptable.
Remarks	None.
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A8.2 Annex Point IIA,VIII.8.2	In case of fire, nature of reaction products, combustion gases, etc.	
		Official use only

Fire-fighting measures

Suitable extinguishing agents:

Water, foam, dry chemical or carbon dioxide. Avoid breathing dusts, vapours and fumes from burning materials.

Protective equipment:

Wear self-contained positive pressure breathing apparatus and full fire fighting protective clothing.

Additional information:

Take note of surrounding materials.
Cool endangered receptacles with water spray.
In case of fire use normal fire fighting equipment

Hazardous decomposition products

Materials to be avoided:

Stable in presence of copper and iron.

Dangerous decomposition products:

Potential decomposition products include HF, HBr, HCl and oxides of nitrogen and carbon.

(Reference: Anonymous, 2005)

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	15/03/2010
Evaluation of applicant's justification	The information provided on fire-fighting measures and hazardous decomposition products appears comprehensive and acceptable.
Conclusion	The applicant's justification is acceptable.
Remarks	None.
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A8.3 Annex Point IIA,VIII.8.3	Emergency measures in case of an accident	Official use only

Emergency measures in case of an accident

Person-related safety precautions:

You are recommended to wear self-contained positive pressure breathing apparatus and full fire fighting protective clothing.
In case of fire use normal fire fighting equipment

Measures for environmental protection:

Do not allow product to reach sewage system or any water course.
This material is soluble in water
Stop water flow or divert water around spill area if safe to do so.
Stop source of spill as soon as possible and notify site or duty manager.
Notify the Emergency Services, National Environment Agency.

X

Measures for cleaning/ collecting:

Cover with dry sand or earth and sweep up and shovel into closable containers for safe disposal. Wash the contaminated spillage area thoroughly with water. Do not allow the wash water to run off into any sewer, stream, well or pond, and if necessary soak it up with more absorbent material. Collect spillages in an appropriate container. Dispose in a manner approved by Local Authority.

First-aid measures

After inhalation:

If symptoms are experienced, move to fresh air and get medical attention.

After skin contact:

Remove all contaminated clothing and thoroughly wash skin with soap and plenty of water. Get medical attention if irritation occurs.

After eye contact:

Flush eyes with clean water for several minutes and call a physician if irritation persists.

After swallowing:

Drink two large glasses of water. Never give anything by

Section A8.3 Annex Point IIA,VIII.8.3	Emergency measures in case of an accident
	mouth to an unconscious person. Induce vomiting by touching back of throat with fingers. Call a physician immediately. **Note to physician:** No specific antidote is known. Symptomatic treatment. (Reference: Anonymous, 2005)
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	15/03/2010
Evaluation of applicant's justification	The information provided on emergency measures in case of an accident and first-aid measures appears comprehensive and acceptable.
Conclusion	The applicant's justification is acceptable.
Remarks	Tralopyril is 'slightly' or 'sparingly' soluble in water.
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

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	
		Official use only
	Measures for environmental protection: Do not allow product to reach sewage system or any water course. This material is only slightly soluble in water Stop water flow or divert water around spill area if safe to do so. Stop source of spill as soon as possible and notify site or duty manager. Notify the Emergency Services, National Environment Agency. **Measures for cleaning/ collecting:** Cover with dry sand or earth and sweep up and shovel into closable containers for safe disposal. Wash the contaminated spillage area thoroughly with water. Do not allow the wash water to run off into any sewer, stream, well or pond, and if necessary soak it up with more absorbent material. Collect spillages in an appropriate container. Dispose in a manner approved by Local Authority. (Reference: Anonymous, 2005)	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	15/03/2010	
Evaluation of applicant's justification	The information provided on the possibility of destruction or decontamination following release appears comprehensive and acceptable.	
Conclusion	The applicant's justification is acceptable.	
Remarks	None.	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A8.5 Annex Point IIA, VIII.8.5	Procedures for waste management of the active substance for industry or professional users	
		Official use only

Section A8.5 Annex Point IIA, VIII.8.5	Procedures for waste management of the active substance for industry or professional users
	Disposal considerations Recommendation: Cover with dry sand or earth and sweep up and shovel into closable containers for safe disposal. Wash the contaminated spillage area thoroughly with water. Do not allow the wash water to run off into any sewer, stream, well or pond, and if necessary soak it up with more absorbent material. Collect spillages in an appropriate container. Dispose in a manner approved by Local Authority. (Reference: Anonymous, 2005)
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	15/03/2010
Evaluation of applicant's justification	The information provided on procedures for waste management of the active substance appears comprehensive and acceptable.
Conclusion	The applicant's justification is acceptable.
Remarks	None.
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A8.5.1 Annex Point IIA,VIII.8.5.1	Possibility of re-use or recycling	
		Official use only
	Please refer to Doc. IIIA, Section A8.5	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	15/03/2010	
Evaluation of applicant's justification	Not applicable.	
Conclusion	Not applicable.	
Remarks	None.	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A8.5.2 Annex Point IIA,VIII.8.5.2	Possibility of neutralisation of effects	
		Official use only
	Please refer to Doc. IIIA, Section A8.5	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	15/03/2010	
Evaluation of applicant's justification	Not applicable.	
Conclusion	Not applicable.	
Remarks	None.	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A8.5.3 Annex Point IIA,VIII.8.5.3	Conditions for controlled discharge including leachate qualities on disposal	
		Official use only
	Please refer to Doc. IIIA, Section A8.5	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	15/03/2010	
Evaluation of applicant's justification	Not applicable.	
Conclusion	Not applicable.	
Remarks	None.	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A8.5.4 Annex Point IIA,VIII.8.5.4	Conditions for controlled incineration	
		Official use only
	Please refer to Doc. IIIA, Section A8.5	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	15/03/2010	
Evaluation of applicant's justification	Not applicable.	
Conclusion	Not applicable.	
Remarks	None.	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

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	
		Official use only
	There are no observations on undesirable or unintended side effects.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	15/03/2010	
Evaluation of applicant's justification	Not applicable.	
Conclusion	Not applicable.	
Remarks	None.	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

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 (OJ No L20,26.1,1980, p.43)**	
		Official use only
	Not applicable to Tralopyril.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	15/03/2010	
Evaluation of applicant's justification	Not applicable.	
Conclusion	Not applicable.	
Remarks	None.	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A9 Classification and Labelling

Subsection				Official use only
9.1.	Hazard symbols	T (Toxic) N (Dangerous for the environment)		
9.2.	Risk phrases	R23/25:	Toxic by inhalation and if swallowed	
		R50/53:	Very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment	
		R55:	Toxic to fauna	
		R57:	Toxic to bees	
9.3.	Safety phrases	S2:	Keep out of reach of children	
		S13:	Keep away from food, drink and animal feeding stuffs	
		S20/21:	When using, do not eat, drink or smoke	
		S37:	Wear suitable gloves	
		S45:	In case of accident or if you feel unwell, seed medical advice immediately (show the label where possible)	
		S61:	Avoid release to the environment. Refer to special instructions/Safety data sheets	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	12/03/2010
Materials and Methods	Not applicable
Results and discussion	Not applicable
Conclusion	Not applicable
Reliability	Not applicable
Acceptability	Acceptable
Remarks	See Doc IIA, Section 1.5.1 for full Classification and Labelling information.
	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	