Document III-A

3-iodo-2-propynyl butylcarbamate

(IPBC)

CAS No. 55406-53-6
from IPBC Task Force
For use as metalworking fluid preservative (Product Type 13)

All studies evaluated in Doc III-A with the PT 8 dossier and most of the justifications for non-submission presented in the PT 8 dossier are applicable for the present dossier for PT 13. In cases where new studies or other information's have been submitted these will be presented here.

Section A1 Applicant

Annex Point IIA1

1.1	**Applicant**	**Name:** European Union IPBC Task Force (**Arch Chemicals, Dow Benelux B.V., ISP Switzerland GmbH, Lanxess Deutschland GmbH, Troy Corp.**), c/o SCC GmbH **Address:** [redacted] **Telephone:** [redacted] **Fax number:** [redacted] E-mail address: [redacted]
1.2	**Manufacturer of Active Substance** (if different)	Confidential information: Please refer to the "Confidential Data File"
1.3	**Manufacturer of Product(s) (if different)**	Not applicable: The Product Dossier is based on a model formulation.
	1) Product 1	
	2) Product n	

Section A2 Identity

[redacted]

Please refer to the "Confidential Data File" for information on Identity

[redacted]

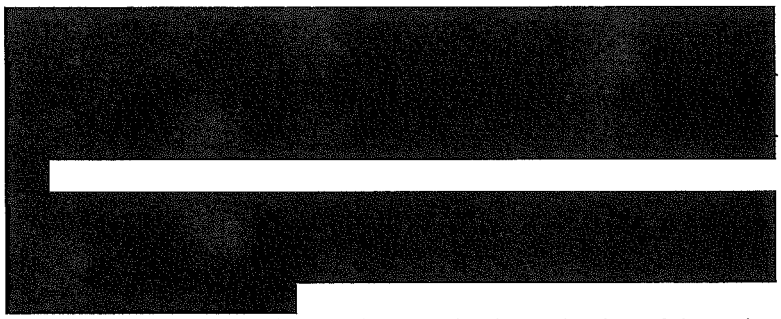
Please find attached a updated confidential files for the respective IPBC TF members in this CA-report in the Confidential files.

Section A3 Physical and Chemical Properties of Active Subst

All data was already submitted in the PT 8 dossier (see Doc IIIA reference list). [redacted] Therefore, no further data on physical chemical properties of the active substance is submitted.

Section A4.1 Analytical Methods for Detection and Identification

Annex Point IIA4.1/4.2 & IIIA-IV.1



A summary of the analytical method for the determination of the active substance in IPBC technical is provided in Doc IIA, chapter 1.4.1.

Section A4.2d/01 Analytical Methods for Detection and Identification

Annex Point IIAIV.4.2 (d) of IPBC and PBC in animal and human body fluids and tissues

Official use only

1 REFERENCE

1.1	**Reference**	Düsterloh, K., (2008). Development and Validation of a Residue Analytical Method for the Determination of IPBC and its metabolite PBC in Body Fluids and Tissue, Itingen, Switzerland: RCC, Study No.: B49443; Doc.-No. 433-002
1.2	**Data protection**	Yes
1.2.1	Data owner	[redacted]
1.2.2	Companies with Letter of Access	[redacted]
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes; European Commission, Guidance Document on Residue Analytical Methods, SANCO/825/00 rev. 7, Jun. 20, 2004
2.2	**GLP**	Yes
2.3	**Deviations**	No

3 MATERIALS AND METHODS

3.1	**Preliminary treatment**	
3.1.1	Enrichment	No enrichment
3.1.2	Cleanup	IPBC and PBC were extracted from blood and urine with acetonitrile:acetic acid, centrifuged and diluted if appropriate. To extract IPBC and its metabolite from meat acetonitrile:HCl was used as extracting GmbHent.
3.2	**Detection**	
3.2.1	Separation method	Reversed phase chromatography on C 18 phase (in confirmatory method a Luna Phenyl-hexyl column used)
3.2.2	Detector	MS/MS detection with positive electrospray ionisation.
3.2.3	Standard(s)	IPBC and PBC standards were prepared in Methanol.
3.2.4	Interfering substance(s)	none
3.3	**Linearity**	
3.3.1	Calibration range	Please refer to table 1
3.3.2	Number of measurements	7 calibration standard solutions for each substance

Section A4.2d/01 Analytical Methods for Detection and Identification

Annex Point IIAIV.4.2 (d) of IPBC and PBC in animal and human body fluids and tissues

3.3.3	Linearity	correlation coefficient r^2 Please refer to table 1
3.4	**Specifity: interfering substances**	There were no interfering substances seen in the blank chromatograms. The specificity was shown by confirmatory methods.
3.5	**Recovery rates at different levels**	Please refer to table 3
3.5.1	Relative standard deviation	Please refer to table 3
3.6	**Limit of determination**	Limit of Detection (LOD) Please refer to table 4 Limit of Quantification (LOQ) Please refer to table 4
3.7	**Precision**	
3.7.1	Repeatability	Please refer to table 3
3.7.2	Independent laboratory validation	Not necessary for a analytical method in body fluids and tissue

Section A4.2d/01 Analytical Methods for Detection and Identification
Annex Point IIAIV.4.2 (d) of IPBC and PBC in animal and human body fluids and tissues

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

IPBC and PBC were extracted from blood and urine with acetonitrile:acetic acid, centrifuged and diluted if appropriate. To extract IPBC and its metabolite from meat acetonitrile:HCl was used as extracting agent.

Analysis was done by HPLC using reversed-phase liquid chromatography and a water / methanol gradient on a C18-column.

Detection was made with a MS/MS system using positive electrospray ionisation.

4.2 Conclusion

Validation data in urine showed recoveries in the range of 67 – 79 % for IPBC and 60 – 87 % for PBC at the concentration levels of 0.05 and 0.5 mg/L.

In blood and muscle IPBC degraded rapidly and it was not possible to determine IPBC residues above 70%. A degradation test was performed and it could be shown that spiked IPBC amounts could be determined as PBC and calculated as IPBC equivalents with mean recoveries of 112 % in blood and 116% in muscle.

These results are in agreement with the toxicological evaluation, where a very rapid degradation of IPBC to PBC was observed (please refer to Section A6.2/01; Annex Point IIA, VI.6.2; Toxicokinetic and metabolism in mammals, Rat, gavage).

For PBC recoveries in the range of 76 – 117 % were obtained in meat and recoveries of 81 – 114 % in blood. This shows that PBC was stable over the period of the experiment.

4.2.1 Reliability [redacted]

4.2.2 Deficiencies No

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Table 1 Calibration range

Matrix	Test substance	lower level	upper level
Blood	IPBC	0.5 ng/mL	12.5 ng/mL
	PBC	0.5 ng/mL	12.5 ng/mL
Urine	IPBC	0.5 ng/mL	12.5 ng/mL
	PBC	0.5 ng/mL	12.5 ng/mL
Meat	IPBC	0.5 ng/mL	12.5 ng/mL
	PBC	0.5 ng/mL	12.5 ng/mL

Table 2 Correlation coefficients for linear calibration

Matrix	Test substance	correlation coefficient R^2
Blood	IPBC	0.9981
	PBC	0.9994
Urine	IPBC	0.9981
	PBC	0.9994
Meat	IPBC	0.9981
	PBC	0.9994

Table 3a Validation data for primary methods

Matrix	Test substance	Fortification level	Recovery rate (%)		RSD	N
			mean	range	(%)	
Blood	PBC	0.05 mg/L	93	81 – 109	13	4
	PBC	0.5 mg/L	103	96 – 114	6	5
Overall	PBC		99	81-114	10	10
Urine	IPBC	0.05 mg/L	76	72 – 79	3	5
	PBC	0.05 mg/L	63	60 – 67	4	5
	IPBC	0.5 mg/L	70	67 – 76	5	5
	PBC	0.5 mg/L	77	73 – 87	7	5
Overall	IPBC		73	67-79	5	10
Overall	PBC		70	60-87	12	10
Meat	PBC	0.1 mg/kg	99	84 – 117	11	5
	PBC	1.0 mg/kg	86	76 – 99	10	5
Overall	PBC		92	76-117	13	10

Table 3b Validation data for confirmatory methods

Matrix	Test substance	Fortification level	Recovery rate (%)		RSD	N
			mean	range	(%)	
Blood	PBC	0.05 mg/L	93	73 – 104	15	3
	PBC	0.5 mg/L	106	106, 106	0	2
Overall	PBC		98	73-106	13	5
Urine	IPBC	0.05 mg/L	100	95-105	4	3
	PBC	0.05 mg/L	83	74-88	8	3
	IPBC	0.5 mg/L	101	99; 103	2	2
	PBC	0.5 mg/L	80	82, 78	3	2
Overall	IPBC		100	95-105	3	5
Overall	PBC		82	74-88	7	5
Meat	PBC	0.1 mg/kg	87	80 – 96	8	3
	PBC	1.0 mg/kg	91	95, 88	4	2
Overall	PBC		89	80-96	7	5

Table 4 Limit of Detection (LOD) and Limit of Quantification (LOQ)

Matrix	Test substance	LOD	LOQ
Blood	IPBC	0.026 mg/mL	0.05 mg/L
	PBC	0.026 mg/mL	0.05 mg/L
Urine	IPBC	0.026 mg/mL	0.05 mg/L
	PBC	0.026 mg/mL	0.05 mg/L
Meat	IPBC	0.050 mg/kg	0.1 mg/kg
	PBC	0.050 mg/kg	0.1 mg/kg

Section A4.3 Annex Point IIA,IV.4.2 (e)	Analytical Methods for Detection and Identification of IPBC in food and feeding stuffs and other products where relevant	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ] Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	Not relevant for Product type 13 (metalworking fluid preservatives)	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	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 A5 Effectiveness against target organisms and intended uses: Active substance IPBC

Subsection (Annex Point)			Official use only
5.1	**Function (IIA5.1)**	Fungicide	
5.2	**Organism(s) to be controlled and products, organisms or objects to be protected (IIA5.2)**	-	
5.2.1	**Organism(s) to be controlled (IIA5.2)**	Fungi . [redacted]The tests provided demonstrate that the active substance IPBC is effective against fungi in metalworking fluids. The lowest tested concentration covers the below cited likely lowest concentration at which IPBC is used in metalworking fluids of 0.005%.	X
5.2.2	**Products, organisms or objects to be protected (IIA5.2)**	PT13: IPBC is a fungicide for metalworking fluid preservation.	
5.3	**Effects on target organisms, and likely concentration at which the active substance will be used (IIA5.3)**	-	
5.3.1	**Effects on target organisms (IIA5.3)**	IPBC is toxic to fungi. Data on the efficacy of IPBC against fungi are provided in the confidential part of [redacted]	X
5.3.2	**Likely concentrations at which the A.S. will be used (IIA5.3)**	IPBC based metalworking fluid preservation products are used in emulsifiable and water soluble metalworking fluids (MWFs) at the following IPBC concentration: Industrial and professional use: Concentration of IPBC in the: Product: 10% - 40% Pre-solution: 0.2% - 4% Metalworking fluid: 0.005% - 0.1% This list is not claimed to be all-inclusive. Additional uses may exist and/or concentrations may be used which are not covered by the exposure and risk assessments provided in this dossier. In this case	

Section A5 Effectiveness against target organisms and intended uses: Active substance IPBC

		such uses or differing concentrations would need to be evaluated on the national level after Annex I inclusion.	
			X
5.4	**Mode of action (including time delay) (IIA5.4)**	-	
5.4.1	**Mode of action**	IPBC has a Carbamate structure. The target sites of Carbamates in fungi are cell membrane permeability and fatty acids (according to the information provided by FRAC (Fungicide Resistance Action Committee) on its website *http://www.frac.info/frac/publication/anhang/FRAC_Code_List2_2006_web.pdf*	X
5.4.2	**Time delay**	Not a relevant point for an metalworking fluid preservative	
5.5	**Field of use envisaged (IIA5.5)**	Include code(s) and term(s)	X
	MG02: Preservatives	IPBC is used in products of the following Product Types: PT06: In-can preservatives PT07: Film preservatives PT08: Wood preservatives PT09: Fibre, leather, rubber and polymerised materials preservatives PT10: Masonry preservatives PT11: Preservatives for liquid-cooling and processing systems PT13: Metalworking preservatives In the present dossier, only the use of IPBC for metalworking fluid is addressed.	
	Further specification		X
5.6	**User (IIA5.6)**		
	Industrial	See above: Doc. IIIA, Section A5.3.2	
	Professional	See above: Doc. IIIA, Section A5.3.2	
	General public	No	
5.7	**Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies (IIA5.7)**		

Section A5 Effectiveness against target organisms and intended uses: Active substance IPBC

5.7.1	**Development of resistance**	IPBC has a Carbamate structure. The target sites of Carbamates in fungi are cell membrane permeability and fatty acids (according to the information provided by FRAC (Fungicide Resistance Action Committee) on its website (see above: Section 5.4.1). The risk of resistance formation against Carbamate fungicides is regarded to be low to medium by FRAC (Fungicide Resistance Action Committee. This applies to the use of Carbamate fungicides in agriculture, where yearly applications to the same fields are possible (even more than one application per season is possible).	
5.7.2	**Management strategies**	Based on the unspecific mode of action for IPBC the risk of resistance formation is regarded to be low and therefore no management strategies need to be developed.	X
5.8	**Likely tonnage to be placed on the market per year (IIA5.8)**	This is a very sensitive requirement. Information on sales volumes will be provided by the TF Members upon request by the RMS.	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM THE NOTIFIER
Date	[redacted]
Results and discussion	
Conclusion	
Reliability	
Acceptability	

Remarks	[redacted]

Section A6.13 Annex Point IIIA, VI.2	Toxic effects on livestock and pets	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [x]	
Detailed justification:	Not required for Product type 6 (in-can preservatives) and Product type 13 (metalworking fluid preservatives).	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section A6.15 Annex Point IIIA, VI.4	Food and feeding stuffs	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ] Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	Not required for Product type 13 (PT13).	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section A7.1.1.2.3 Annex Point IIIA, XII.2.1	Biodegradation in seawater	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	According to the TNsG on data requirements a seawater biodegradation test is not required for product type PT 13 (metalworking fluid preservatives). • Therefore, a study on seawater biodegradation is not regarded to be warranted for IPBC.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	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 A7.1.2.1.2 Annex Point IIIA, XII.2.1	Anaerobic biodegradation	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA **Other justification**	Official use only
Detailed justification:	According to the TNsG on data requirements, an anaerobic biodegradation study is not required for product type PT 13 (metalworking fluid preservatives). Therefore, a study on anaerobic biodegradation is not regarded to be warranted for IPBC.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	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 A7.3.1/01 Phototransformation in air (estimation method)

Annex Point IIIA, VII.5

Official use only

1 REFERENCE

1.1	**Reference**	Görg, J., Glöckner, Th. (2007): Estimation of photochemical degradation of IPBC using the Atkinson calculation method; Scientific Consulting Company, Chemisch-Wissenschaftliche Beratung GmbH, 55234 Wendelsheim, Germany; Doc. No. 743-002; 08.06.2007; (unpublished)
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Not applicable; model calculation according to the Atkinson calculation method.
2.2	**GLP**	No; study is a model calculation.
2.3	**Deviations**	Not applicable.

3 MATERIAL AND METHODS

3.1	**Test material**	Not applicable.
3.2	**Reference substance**	Not applicable.
3.3	**Test solution**	Not applicable.
3.4	**Testing procedure**	The photochemical and oxidative decomposition of IPBC in air was evaluated based on theoretical grounds by a calculation according to Atkinson. The calculation was performed with the help of the programme AOPWIN, Atmospheric Oxidation Programme v1.92 for Microsoft Windows 3.1, Windows 95/98, Windows NT (© 2000 US Environmental Protection Agency).

4 RESULTS

4.1	**OH radical reaction rate constant k_{OH}**	[redacted]

Section A7.3.1/01 Phototransformation in air (estimation method)

Annex Point IIIA, VII.5

[redacted]

4.2 Ozone reaction rate constant k_{Ozone}

[redacted]

4.3 Atmospheric half-life using k_{OH}

[redacted]

4.4 Atmospheric half-life using k_{Ozone}

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The photochemical and oxidative decomposition of IPBC in air was evaluated based on theoretical grounds by a calculation according to Atkinson.

5.2 Results and discussion

5.2.1 Reaction rate

$k_{OH} = 25.5485 \times 10^{-12}$ cm^3 molecule^{-1} sec^{-1}.

Section A7.3.1/01 Phototransformation in air (estimation method)

Annex Point IIIA, VII.5

	constant	$k_{Ozone} = 42.0 \times 10^{-22}$ cm^3 molecule^{-1} sec^{-1}.
5.2.2	**Tropospherical half life**	The DT_{50} for IPBC is estimated to be 0.628 days (24-hr day), corresponding to 15.072 hours using k_{OH}. The DT_{50} for IPBC was estimated to be 2728.568 days using k_{Ozone}.
5.3	**Conclusion**	IPBC degrades quickly in the atmosphere by reacting with OH radicals, having a DT50 value of 0.628 days (24-hr day), corresponding to 15.072 hours. It also reacts with ozone, but with a longer reaction time: The DT50 is 2728.568 days. Considering the fact that IPBC is only slightly volatile (vapour pressure = 1.4 x 10^{-3} Pa), a significant pollution of the air by the use of IPBC can be excluded.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	No

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
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*
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 A7.3.2 Annex Point IIIA, XII.3	Fate and behaviour in air, further studies	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	According to the TNsG on data requirements an experimental estimation of the fate and behaviour in air is only required if the active substance is to be used in preparations form fumigants or causes risk to the atmospheric environment. [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	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	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 A7.5.2.1 Annex Point IIIA, XIII.3.2	Reproduction study with earthworm or other soil non-target organisms	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Scientifically unjustified	
Detailed justification:	According to the BPD 98/8/EC and the TNsG on data requirements, long-term terrestrial tests are required if the risk assessment for the terrestrial compartment still indicates a concern for the terrestrial compartment. [redacted] • [redacted]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	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*	

Section A7.5.2.2 Annex Point IIIA, XIII.3.2	Long-term test with terrestrial plants	
Detailed justification:	**JUSTIFICATION FOR NON-SUBMISSION OF DATA** **Scientifically unjustified** According to the BPD 98/8/EC and the TNsG on data requirements, long-term terrestrial tests are required if the risk assessment for the terrestrial compartment still indicates concern for the terrestrial compartment or if there is long term exposure. [redacted] [redacted] • [redacted]	Official use only
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	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*	

Section A7.5.3.1.1 Annex Point IIIA, XIII.1.1	Acute oral toxicity to birds	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 13 (metalworking fluid preservatives).	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	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*	

Section A7.5.3.1.2 Annex Point IIIA, XIII.1.2	Short-term toxicity to birds	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 13 (metal working fluid preservatives).	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	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*	

Section A7.5.3.1.3 **Annex Point IIIA, XIII.1.3**	**Effects on reproduction of birds**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 6 (in-can preservatives) and Product type 13 (metalworking fluid preservatives).	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	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*	

Section A7.5.4.1 **Annex Point IIIA, XIII.3.1**	**Acute toxicity to honeybees and other beneficial arthropods**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 6 (in-can preservatives) and Product type 13 (metalworking fluid preservatives).	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	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*	

Section A7.5.6 Annex Point IIIA, XIII.3	Effects on other terrestrial non-target organisms	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	According to the BPD 98/8/EC and the TNsG on data requirements, further tests with other terrestrial non-target organisms may be required if the risk assessment based on long-term terrestrial tests show that there is still a concern for the terrestrial compartment. • [redacted]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	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*	

Section A7.5.7.1.1 Annex Point IIIA, XIII.3.4	Acute oral toxicity to mammals	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 13 (metalworking fluid preservatives).	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	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*	

Section A7.5.7.1.2 Annex Point IIIA, XIII.3.4	Short-term toxicity to mammals	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 13 (metalworking fluid preservatives).	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	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*	

Section A7.5.7.1.3 Annex Point IIIA, XIII.3.4	Effects on reproduction of mammals	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 6 (in-can preservatives) and Product type 13 (metalworking fluid preservatives).	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	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*	

Section A7.6	Summary of ecotoxicological effects and fate and behavior in the environment
	This section number is covered by Document IIA of the dossier.

Section A8.1- A8.7 Measures necessary to protect man, animals and the environment

	The information provided in the PT 8 dossier is applicable for Product type PT 6 (in-can preservatives) and Product type PT 13 (metalworking fluid preservatives).

9 CLASSIFICATION AND LABELLING

The following harmonised classification and labelling for the active substance IPBC is valid:

Harmonised classification/labelling according to Directive 67/548/EEC for the active substance, IPBC, following evaluation

Classification
Class of danger T, N
Toxic, Dangerous for the environment

R phrases	R22	Harmful if swallowed.
	R23	Toxic by inhalation
	R48/23	Danger of serious damage to health by prolonged exposure through inhalation
	R41	Risk of serious damage to the eye
	R43	May cause sensitization by skin contact
	R50	Very toxic to aquatic organisms.
S phrases	S1	Keep locked up.
	S23	Do not breathe vapour/spray
	S24/25	Avoid contact with skin and eyes
	S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
	S36/37/39	Wear suitable protective clothing, gloves and eye/face protection.
	S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
	S61	Avoid release to the environment. Refer to special instructions/Safety data sheets.

Proposed classification based on Regulation EC 1272/2008:

Signal Word	Danger
Pictograms	GHS05, GHS06, GHS09
Hazard class and category code(s)	Acute Tox 3 Eye Dam. 1 Acute Tox 4 Skin Sens. 1 STOT RE1 Aquatic Acute 1 Aquatic Chronic 1*
H-Statements	H331: Toxic if inhaled

H318: Causes serious eye damage
H302: Harmful if swallowed
H317: May cause an allergic skin reaction

H372 (larynx): Causes damage to organs through prolonged or repeated exposure

H400: Very toxic to aquatic life
H410: Very toxic to aquatic life with long-lasting effects*

Environmental M-factor 10 (acute), 1 (chronic)

Precautionary statements according to the latest classification and labelling guidance No. 1272/2008 have not been assigned.

The classification and labeling of IPBC is included in Annex VI of the CLP regulation (6th ATP to the CLP Regulation; Commission Regulation (EU) No 605/2014 of 5 June 2014).

Section A10 Summary and Evaluations of Sections 2 to 9

Please refer to Doc. IIA.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A3.1.1/01 Submitted with the PT8 BPD dossier	Jungheim	2000	Preventol MP 100 - Physicochemical properties Source: Bayer AG, Leverkusen, Germany Report No.: N 00/0070/02 LEV GLP; (unpublished) Doc. No.: 112-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A3.1.1/02 Submitted with the PT8 BPD dossier	Rodriguez, O.	1990	Melting Point of TROYSAN Polyphase P100 3-Iodo-2-Propynyl Butyl Carbamate Source: Troy Corporation, USA Report No.: TC-0236 TAL 8/20/90 GLP; (unpublished) Doc. No.: 112-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A3.1.1/03 Submitted with the PT8 BPD dossier	Polson, G.	1994	Physical and chemical properties of 3-iodo-2-propynylbutylcarbamate (Omacide IPBC) Source: Olin Research Center, Cheshire Report No.: 93B02IPBC GLP; (unpublished) Doc. No.: 119-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A3.1.1/04 Submitted with the PT8 BPD dossier	Morrissey, M.A.	1997	Product chemistry determinations of IPEX 1000 (Color, Physical State) Source: Corning Hazleton Inc., Virginia, USA Report No.: CHW 6752-101 GLP; (unpublished) Doc. No.: 119-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	DOW Benelux B.V.
A3.1.3/01 Submitted with the PT8 BPD dossier	Anonymous	1990	True density of TROYSAN Polyphase P100 Source: Quantachrome Corporation, N.Y., United States Report No.: TC-0246 90-1478 GLP; (unpublished) Doc. No.: 113-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A3.2.1/01 Submitted with the PT8 BPD dossier	Görg, J.	2004	Calculation fo the Henry´s Law Constant - Active Substance IPBC 3-Iodo-2-propynyl-butylcarbamate Source: Scientific Consulting Company, Wendelsheim, Germany Report No.: 824-006 Not GLP; (unpublished) Doc. No.: 115-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, ISP, LANXESS, DOW, TROY)
A3.2/01 Submitted with the PT8 BPD dossier	Olf	2000	Preventol MP 100 - Vapor pressure, Physical-chemical properties Source: Bayer AG, Leverkusen, Germany Report No.: 00/024/01 GLP; (unpublished) Doc. No.: 115-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A3.2/02 Submitted with the PT8 BPD dossier	Schneider, U.	2002	Final Report: IPBC Determination of the Vapour Pressure Source: Infracor Chemistry Services Report No.: AN-ASB 0202 GLP; (unpublished) Doc. No.: 115-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	DOW Benelux B.V.
A3.4/01 Submitted with the PT8 BPD dossier	Seelemann	2000	Preventol MP 100 - Identity/ Spectra Source: Bayer AG, Leverkusen, Germany Report No.: N 00/0070/00 LEV GLP; (unpublished) Doc. No.: 117-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A3.4/02 Submitted with the PT8 BPD dossier	Anonymous	1997	Spectra for IPBC: GC-MS, UV, IR Source: Olin Central analytical Laboratory, Cheshire Report No.: grl 2/6/97 Not GLP; (unpublished) Doc. No.: 117-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A3.4/03 Submitted with the PT8 BPD dossier	Lloyd, G.R.	1997	3-Iodo-Propynyl-Butyl-Carbamate (IPBC) - NMR traces Source: Olin Central analytical Laboratory, Cheshire Report No.: 19/8/97 Not GLP; (unpublished) Doc. No.: 117-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A3.4/04 Submitted with the PT8 BPD dossier	Wojcieck, B.C.	1994	IPBC - Ultraviolet-Visible Absorption Spectrum (Amended Report) Source: Ricerca, LLC, Painesville OH Report No.: TC-0617 4257-93-0276-AS-001-002 GLP; (unpublished) Doc. No.: 117-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A3.5/01 Submitted with the PT8 BPD dossier	Morrissey, M.A.	1997	Solubility determination of IPEX 1000 Source: Covance Laboratories Inc., Virginia Report No.: Covance 6752-105 GLP; (unpublished) Doc. No.: 114-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	DOW Benelux B.V.
A3.5/02 Submitted with the PT8 BPD dossier	Jungheim	2000	Preventol MP 100 - Water solubility Source: Bayer AG, Leverkusen, Germany Report No.: N 00/0070/03 LEV GLP; (unpublished) Doc. No.: 114-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A3.5/03 Submitted with the PT8 BPD dossier	Cameron, B.D. Machon, A.	1986	The solubility of IPBC in buffers pH 5.0, 7.0 and 9.0 incubated at 25 °C Source: Inveresk Research Institute Report No.: TC-0244 135124 4166 GLP; (unpublished) Doc. No.: 114-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A3.6/01 Submitted with the PT8 BPD dossier	Siemann, L.	1990	Analysis of Polyphase P100 - Dissociation Constant (63-10) Source: Midwest Research Institute, Kansas City, United States Report No.: TC-0247 9555-F(01) GLP; (unpublished) Doc. No.: 115-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A3.9/01 Submitted with the PT8 BPD dossier	Jungheim	2000	Preventol MP 100 - Partition coefficient (n-octanol/water) Source: Bayer AG, Leverkusen, Germany Report No.: N 00/0070/04 LEV GLP; (unpublished) Doc. No.: 114-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A3.9/02 Submitted with the PT8 BPD dossier	Siemann, L.	1990	Analysis of Polyphase P100 - Octanol/Water Partition coefficient (63-11) Source: Midwest Research Institute, Kansas City, United States Report No.: TC-0248 9555-F (01) GLP; (unpublished) Doc. No.: 114-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A3.10/01 Submitted with the PT8 BPD dossier	Polson, G.	1997	Physical and chemical properties of 3-Iodo-2-Propynylbutylcarbamate (IPBC-100) Source: Olin Central analytical Laboratory, Cheshire Report No.: 18-94B07IPBC GLP; (unpublished) Doc. No.: 146-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A3.10/02 Submitted with the PT8 BPD dossier	Lezotte, F. MacGregor, J. Chafey, K. Nixon, W.B.	2001	Determination of storage stability of IPBC technical (PROTRAM 98) at ambient and elevated temperatures (Interim Report - Elevated temperature phase) Source: Wildlife International Ltd., Easton, Maryland, USA Report No.: 526C-103 GLP; (unpublished) Doc. No.: 146-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	DOW Benelux B.V.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A3.10/03 Submitted with the PT8 BPD dossier	Sinning, D.J.	1999	Physical and Chemical Characteristics of TROYSAN Polyphase 100 - Stability Source: Case Consulting Laboratories, Inc., Whippany, N.J., United States Report No.: TC-0926 650-25 GLP; (unpublished) Doc. No.: 146-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A3.11/01 Submitted with the PT8 BPD dossier	Lindemann, M.	2004	Determination of the flammability of IPBC technical Source: Research and Consulting Company, Itingen, Switzerland Report No.: 851398 GLP; (unpublished) Doc. No.: 142-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, DOW, LANXESS, TROY)
A3.11/02 Submitted with the PT8 BPD dossier	Lindemann, M.	2004	Determination of the relative self-ignition temperature of IPBC technical Source: Research and Consulting Company, Itingen, Switzerland Report No.: 851402 GLP; (unpublished) Doc. No.: 142-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, DOW, LANXESS, TROY)
A3.13/01 Submitted with the PT8 BPD dossier	Olf	2000	Preventol MP 100 - Surface tension, physical-chemical properties Source: Bayer AG, Leverkusen, Germany Report No.: 00/024/03 GLP; (unpublished) Doc. No.: 116-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A3.15 Submitted with the PT8 BPD dossier	Görg, J.	2005	Statement on the explosive properties of 3-Iodopropynylbutyl Carbamate (IPBC) Source: Scientific Consulting Company, Wendelsheim, Germany Report No.: 824-009 Not GLP; (unpublished) Doc. No.: 141-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, DOW, ISP, LANXESS, TROY)
A3.16 Submitted with the PT8 BPD dossier	Görg, J.	2005	Statement on the oxidising properties of 3-Iodopropynylbutyl Carbamate (IPBC) Source: Scientific Consulting Company, Wendelsheim, Germany Report No.: 824-009 Not GLP; (unpublished) Doc. No.: 143-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, DOW, ISP, LANXESS, TROY)

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A4.1/01 Submitted with the PT8 BPD dossier	Anonymous	1993	Water quality - determination of sodium and potassium - Part 1: Determination of sodium by atomic absorption spectrometry Source: International Organization for Standardization, Switzerland, International Standard, ISO 9964-1, First edition 1993-05-01; UDC 614.777:556.114:543.42:546.33 Report No.: ISO 9964-1:1993(E) Not GLP; (published) Doc. No.: 492-003	No	N.R.
A4.1/02 Submitted with the PT8 BPD dossier	Anonymous	N.I.	MT 81 Soluble Alkalinity Source: Miscellaneous Techniques and Impurities, pp. 215-217 Report No.: Not applicable Not GLP; (published) Doc. No.: 492-004	No	N.R.
A4.2a/01 Submitted with the PT8 BPD dossier	Bruckhausen, P.	2004	Development and validation of a residue analytical method for IPBC and its metabolite PBC in soil Source: Research and Consulting Company, Itingen, Switzerland Report No.: 851400 GLP; (unpublished) Doc. No.: 434-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, LANXESS, DOW, TROY)
A4.2c/01 Submitted with the PT8 BPD dossier	Bruckhausen, P.	2004	Development and validation of the residue analytical method for the determination of IPBC and ist metabolite PBC in drinking, ground and surface water Source: Research and Consulting Company, Itingen, Switzerland Report No.: 851401 GLP; (unpublished) Doc. No.: 435-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, DOW, LANXESS, TROY)
A4.2d/01 Submitted with the PT6 BPD dossier	Reisinger, T.	2008	Summary of Preliminary Results - Development and validation of the residue analytical method for the determination of IPBC and its metabolite PBC in Body Fluids and Tissue Source: Scientific Consulting Company, Wendelsheim, Germany Report No.: B49443 Not GLP; (unpublished) Doc. No.: 433-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, DOW, ISP, LANXESS, TROY)
A4.2d/01 Submitted with the PT6 BPD dossier	Düsterloh, K.	2008	IPBC, PBC - Development and validation of a residue analytical method for the determination of IPBC and its metabolite PBC in body fluids and tissue. Source: RCC Ltd, Itingen Switzerland Report No.: B49443 GLP; (unpublished) Doc No. 433-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, DOW, ISP, LANXESS, TROY)

Section No./ Reference No.	Author(s)	Year	Title Source Report GLP; Doc. No. (laboratory) No. (un)published	Data protection	Owner
A6.1.1/01 Submitted with the PT8 BPD dossier	XXXX	2000	Preventol MP 100 - Acute oral toxicity study in male and female wistar rats Source: XXXX Report No.: XXXX 30455 T4069982 GLP; (unpublished) Doc. No.: 521-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A6.1.2/01 Submitted with the PT8 BPD dossier	XXXX	2000	Preventol MP 100 - Acute dermal toxicity study in male and female wistar rats Source: XXXX Report No.: XXXX 30454 T3069981 GLP; (unpublished) Doc. No.: 522-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A6.1.3/01 Submitted with the PT8 BPD dossier	XXXX	1985	Acute inhalation limit test in rats 3-iodo-2-propynyl butyl carbamate Source: XXXX Report No.: TC-0007 Not GLP; (unpublished) Doc. No.: 523-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.1.3/02 Submitted with the PT8 BPD dossier	XXXX	1990	TROYSAN Polyphase P-100 - Acute inhalation toxicity study in the rat Source: XXXX Report No.: TC-0004 90-8277 GLP; (unpublished) Doc. No.: 523-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.1.4/01 Submitted with the PT8 BPD dossier	XXXX	2000	Acute skin irritation test (patch test) of Preventol MP 100 in rabbits Source: XXXX Report No.: XXXX 7891 9300/450/95 XXXX 8069193 GLP; (unpublished) Doc. No.: 565-008	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A6.1.4/02 Submitted with the PT8 BPD dossier	XXXX	1998	Primary eye irritation - IPEX 1000 Source: XXXX Report No.: 6042 GLP; (unpublished) Doc. No.: 566-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	DOW Benelux B.V.
A6.1.5/01 Submitted with the PT8 BPD dossier	XXXX.	1998	Dermal sensitization test - Buehler Method - IPEX 1000 Source: XXXX Report No.: 6044 GLP; (unpublished) Doc. No.: 567-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	DOW Benelux B.V.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A6.1.5/02 Submitted with the PT8 BPD dossier	XXXX	1993	TROYSAN Polyphase P-100 - The guinea pig maximization test Source: XXXX Report No.: TC-0020 14148 GLP; (unpublished) Doc. No.: 567-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.1.5/03 Submitted with the PT8 BPD dossier	XXXX	2001	Preventol MP 100 - Study for the skin sensitization effect in guinea pigs (Guinea pig maximization test according to Magnusson and Kligman) Source: XXXX Report No.: XXXX 30653 XXXX 5069983 GLP; (unpublished) Doc. No.: 567-010	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A6.2/01 Submitted with the PT8 BPD dossier	XXXX	1995	Metabolism of 14C-IPBC in rats Source: XXXX Report No.: XXXX 6491-100 TC-0457 GLP; (unpublished) Doc. No.: 512-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.2/02 Submitted with the PT8 BPD dossier	XXXX	1995	The in vitro percutaneous absorption through human abdominal epidermis of [14C]-IPBC (3-Iodo-2-Propynyl-N-Butyl-Carbamate) Source: XXXX Report No.: 155046 12367 TC0510 GLP; (unpublished) Doc. No.: 511-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.3.1/01 Submitted with the PT8 BPD dossier	XXXX	2001	Preventol MP 100 - 3-iodo-2-propynyl-n-butyl carbamate (IPBC) - Study for subacute oral toxicity in rats (gavage study over 4 weeks and 2 weeks recovery period) Source: XXXX Report No.: XXXX 30948 T6069830 GLP; (unpublished) Doc. No.: 532-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A6.3.1/02 Submitted with the PT8 BPD dossier	XXXX	1986	Iodopropynylbutyl carbamate (IPBC) 4 week dieatry dose range finding study in rats Source: XXXX Report No.: TC-0130 435046 3623 GLP; (unpublished) Doc. No.: 532-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A6.3.1/03 Submitted with the PT8 BPD dossier	XXXX	1986	Establishment of methodology and the routine analysis of Iodopropynylbutyl Carbamate in diets prepared for a 4 week dose range finding study (XXXX Project No. 435046) in the Rat Source: XXXX Report No.: 335018 4224 TC0409b GLP; (unpublished) Doc. No.: 437-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.3.1/04 Submitted with the PT8 BPD dossier	XXXX	1996	A 2-week range-finding study of TROYSAN Polyphase P100 in the rabbits via dietary administration Source: XXXX Report No.: 95-2395 TC0477 GLP; (unpublished) Doc. No.: 531-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.3.1/05 Submitted with the PT8 BPD dossier	XXXX	1987	Iodopropynylbutyl carbamate (IPBC) 8 week dietary dose range finding study in mice Source: XXXX Report No.: 5021 436144 TC0409c GLP; (unpublished) Doc. No.: 533-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.3.3/01 Submitted with the PT8 BPD dossier	XXXX	1994	Omacide IPBC - 2-week repeat dose inhalation toxicity study in rats Source: XXXX Report No.: XXXX 6/932373 GLP; (unpublished) Doc. No.: 531-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A6.3.3/02 Submitted with the PT8 BPD dossier	XXXX	1994	Omacide IPBC - 5-day repeat dose inhalation toxicity study in rats Source: XXXX Report No.: XXXX 8/942212 GLP; (unpublished) Doc. No.: 531-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A6.4.1/01 Submitted with the PT8 BPD dossier	XXXX	2002	Repeated dose toxicity 90-day oral toxicity study in rats with IPBC technical (Protram TM 98) Source: XXXX Report No.: 20-4-0132-01 GLP; (unpublished) Doc. No.: 533-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	DOW Benelux B.V.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A6.4.1/02 Submitted with the PT8 BPD dossier	XXXX	1984	90-Day subchronic oral toxicity test in rats Source: XXXX Report No.: TC-0117 GLP; (unpublished) Doc. No.: 533-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.4.1/03 Submitted with the PT8 BPD dossier	XXXX	1997	A subchronic (3-month) toxicity study of TROYSAN Polyphase P100 in the rabbits via dietary administration Source: XXXX Report No.: 95-2396 TC0478 GLP; (unpublished) Doc. No.: 533-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.4.2/01 Submitted with the PT8 BPD dossier	XXXX	1991	91-day dermal toxicity study in rats with TROYSAN Polyphase P-100 Source: XXXX Report No.: TC-0113 3228.14 GLP; (unpublished) Doc. No.: 534-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.4.3/01 Submitted with the PT8 BPD dossier	XXXX	1994	Omacide IPBC - 13-week inhalation toxicity study in rats Source: XXXX Report No.: XXXX 7/942772 GLP; (unpublished) Doc. No.: 535-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A6.4.3/02 Submitted with the PT8 BPD dossier	Anonymous	1995	Plasma, Erythrocyte and Brain Cholinesterase Background Data Source: Not applicable Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 535-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A6.6.1/01 Submitted with the PT8 BPD dossier	Herbold, B.	2001	Preventol MP 100 - Salmonella/Microsome test plate incorporation and preincubation method Source: Bayer AG, Leverkusen, Germany Report No.: PH 30864 T0069537 GLP; (unpublished) Doc. No.: 557-008	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A6.6.2/01 Submitted with the PT8 BPD dossier	XXXX	2001	Preventol MP 100 - In vitro chromosome aberration test with chinese hamster V79 cells Source: XXXX Report No.: XXXX 30824 T1069538 GLP; (unpublished) Doc. No.: 557-007	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A6.6.3/01 Submitted with the PT8 BPD dossier	XXXX	2001	Preventol MP 100 - V79/HPRT-Test in vitro for the detection of induced forward mutations Source: XXXX Report No.: XXXX 31132 T2069539 GLP; (unpublished) Doc. No.: 557-009	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A6.6.4/01 Submitted with the PT8 BPD dossier	XXXX	1993	Omacide IPBC - Micronucleus cytogenetic assay in mice Source: XXXX Report No.: XXXX 727.122 GLP; (unpublished) Doc. No.: 557-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A6.7/01 Submitted with the PT8 BPD dossier	XXXX	1989	3-iodo-2-propynyl butyl carbamate (IPBC) 104 week dietary carcinogenicity study in rats (Volume 1 and 2) Source: XXXX Report No.: TC-0411 435580 GLP; (unpublished) Doc. No.: 537-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.7/02 Submitted with the PT8 BPD dossier	XXXX	1988	3-iodo-2-propynyl butyl carbamate (IPBC) chronic dietary toxicity study in rats Source: XXXX Report No.: 5261 XXXX 435580 TC1417 GLP; (unpublished) Doc. No.: 537-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.7/03 Submitted with the PT8 BPD dossier	XXXX	1995	Review and interpretation of selected thyroid and forestomach lesions in the carcinogenicity study of 3-iodo-2-propynyl butyl carbamate (IPBC) in sprague-dawley rats Source: XXXX Report No.: TC-0476 Not GLP; (unpublished) Doc. No.: 581-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.7/04 Submitted with the PT8 BPD dossier	XXXX	1989	IPBC 78 week dietary carcinogenicity study in mice Volume 1 to 3 (803 pages) Source: XXXX Report No.: TC-0409 7304 436165 GLP; (unpublished) Doc. No.: 555-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A6.7/05 Submitted with the PT8 BPD dossier	XXXX	1989	IPBC 78 week dietary carcinogenicity study in mice Volume 2 to 3 (803 pages) Source: XXXX Report No.: TC-0409 XXXX 7304 GLP; (unpublished) Doc. No.: 555-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.7/06 Submitted with the PT8 BPD dossier	XXXX	1989	IPBC 78 week dietary carcinogenicity study in mice Volume 2 continued to 3 (803 pages) Source: XXXX Report No.: TC-0409 XXXX 7304 GLP; (unpublished) Doc. No.: 555-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.7/07 Submitted with the PT8 BPD dossier	XXXX	1989	IPBC 78 week dietary carcinogenicity study in mice Volume 3 to 3 (803 pages) Source: XXXX Report No.: TC-0409 XXXX 7304 GLP; (unpublished) Doc. No.: 555-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.7/08 Submitted with the PT8 BPD dossier	XXXX	1995	Pathology working group (PWG) report on the 78-week dietary carcinogenicity study of 3-iodo-2-propynyl butyl carbamate (IPBC) in cd-1-mice Source: Not indicated Report No.: TC-0458 275-003 GLP; (unpublished) Doc. No.: 555-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.7/09 Submitted with the PT8 BPD dossier	XXXX	1988	Results of dietary analysis for IPBC for the 78 week study in mice Source: XXXX Report No.: 436165 336802 GLP; (unpublished) Doc. No.: 437-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.8.1/01 Submitted with the PT8 BPD dossier	XXXX	1994	Omacide IPBC - Oral (Gavage) rabbit developmental toxicity dose ranging study Source: XXXX Report No.: XXXX /20/R GLP; (unpublished) Doc. No.: 551-007	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A6.8.1/02 Submitted with the PT8 BPD dossier	XXXX	1994	Omacide IPBC - Oral (Gavage) rabbit developmental toxicity study Source: XXXX Report No.: XXXX /26/R GLP; (unpublished) Doc. No.: 551-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A6.8.1/03 Submitted with the PT8 BPD dossier	XXXX	1994	Omacide IPBC - Oral (Gavage) rat development toxicity dose ranging study Source: XXXX Report No.: XXXX /18/R GLP; (unpublished) Doc. No.: 551-009	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A6.8.1/04 Submitted with the PT8 BPD dossier	XXXX	1994	Omacide IPBC - Oral (Gavage) rat development toxicity (Teratogenicity) study Source: XXXX Report No.: XXXX /19/R GLP; (unpublished) Doc. No.: 551-008	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A6.8.2/01 Submitted with the PT8 BPD dossier	XXXX	1996	Omacide IPBC - Oral (Gavage) rat one generation (expanded to two generation) reproductive toxicity study (3 Volumes) Source: XXXX Report No.: XXXX /28/R GLP; (unpublished) Doc. No.: 553-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A6.8.2/02 Submitted with the PT8 BPD dossier	XXXX	2003	Historical control data - Reprotoxicity study in rats (Background Pregnancy Data from Multigeneration, Fertility and Pre- and Post Natal Studies on the Sprague-Dawley rat Source: XXXX Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 553-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A6.8.2/03 Submitted with the PT8 BPD dossier	XXXX	1986	TROYSAN Polyphase - Preliminary study for a two generation oral reproduction study in the male sprague dawley rat Source: XXXX Report No.: TC-0126 547-511/2 GLP; (unpublished) Doc. No.: 553-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.8.2/04 Submitted with the PT8 BPD dossier	XXXX	1986	TROYSAN Polyphase preliminary study for a two generation oral reproduction study in the female Sprague Dawley Rat Source: XXXX Report No.: 546-511/1 TC1390 GLP; (unpublished) Doc. No.: 553-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A6.8.2/05 Submitted with the PT8 BPD dossier	XXXX	1987	TROYSAN Polyphase two generation oral (dietary administration) reproduction toxicity study in the rat (one litter per generation) Source: XXXX Report No.: TC-0128 548-511/3 GLP; (unpublished) Doc. No.: 553-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.8.2/06 Submitted with the PT8 BPD dossier	XXXX	2004	Historical control data of two/one generation oral (Dietary Administration) reproduction toxicity studies 1984 to 1990 Source: XXXX Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 553-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.8.2/07 Submitted with the PT8 BPD dossier	Shaw, D.	2004	To whom it may concern - IPBC purity Source: Troy Corporation, USA Report No.: Not applicable Not GLP; (unpublished) Doc. No.: 593-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.9/01 Submitted with the PT8 BPD dossier	XXXX	2002	Acute oral dose range-finding study with 3-iodopropynylbutyl carbamate (IPBC) administered by Gavage in CD rats Source: XXXX Report No.: 7071-100 TC-1414 GLP; (unpublished) Doc. No.: 541-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation ARCH Chemicals
A6.9/02 Submitted with the PT8 BPD dossier	XXXX	2001	Acute oral neurotoxicity study with 3-iodopropynylbutyl carbamate (IPBC) administered by gavage in CD rats - Volume 1 of 3 Source: XXXX Report No.: 7071-101 TC-1059 GLP; (unpublished) Doc. No.: 541-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals TROY Corporation
A6.9/03 Submitted with the PT8 BPD dossier	XXXX	2001	Acute oral neurotoxicity study with 3-iodopropynylbutyl carbamate (IPBC) administered by gavage in CD rats - Volume 2 of 3 Source: XXXX Report No.: 7071-101 TC-1059 GLP; (unpublished) Doc. No.: 541-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals TROY Corporation

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A6.9/04 Submitted with the PT8 BPD dossier	XXXX	2001	Acute oral neurotoxicity study with 3-iodopropynylbutyl carbamate (IPBC) administered by gavage in CD rats - Volume 3 of 3 Source: XXXX Report No.: 7071-101 TC-1059 GLP; (unpublished) Doc. No.: 541-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals TROY Corporation
A6.9/05 Submitted with the PT8 BPD dossier	XXXX	2002	2-week dietary range-finding and palatability study with 3-iodopropynylbutyl carbamate (IPBC) in CD rats Source: XXXX Report No.: 7071-102 TC 1415 GLP; (unpublished) Doc. No.: 542-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation ARCH Chemicals
A6.9/06 Submitted with the PT8 BPD dossier	XXXX	2001	13-week dietary neurotoxicity study with 3-iodopropynylbutyl carbamate (IPBC) in CD rats Volume 1 of 4 Source: XXXX Report No.: 7071-103 TC-1060 GLP; (unpublished) Doc. No.: 542-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals TROY Corporation
A6.9/07 Submitted with the PT8 BPD dossier	XXXX	2001	13-week dietary neurotoxicity study with 3-iodopropynylbutyl carbamate (IPBC) in CD rats Volume 2 of 4 Source: XXXX Report No.: 7071-103 TC-1060 GLP; (unpublished) Doc. No.: 542-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals TROY Corporation
A6.9/08 Submitted with the PT8 BPD dossier	XXXX	2001	13-week dietary neurotoxicity study with 3-iodopropynylbutyl carbamate (IPBC) in CD rats Volume 3 of 4 Source: XXXX Report No.: 7071-103 TC-1060 GLP; (unpublished) Doc. No.: 542-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation ARCH Chemicals
A6.9/09 Submitted with the PT8 BPD dossier	XXXX	2001	13-week dietary neurotoxicity study with 3-iodopropynylbutyl carbamate (IPBC) in CD rats Volume 4 of 4 Source: XXXX Report No.: 7071-103 TC-1060 GLP; (unpublished) Doc. No.: 542-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals TROY Corporation

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A6.9/10 Submitted with the PT8 BPD dossier	XXXX	1996	Acute Neurotoxicity Validation Study with Paraoxon in Rats Source: XXXX Report No.: XXXX 2100-004 Not GLP; (unpublished) Doc. No.: 541-007	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation ARCH Chemicals
A6.9/11 Submitted with the PT8 BPD dossier	XXXX	1996	Neurotoxicity Validation Study with Acrylamide in Rats Source: XXXX Report No.: XXXX 2100-030 Not GLP; (unpublished) Doc. No.: 541-008	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation ARCH Chemicals
A6.11/01 Submitted with the PT8 BPD dossier	XXXX	1988	Polyphase cholinesterase inhibition study in rats Source: XXXX Report No.: TC-0122 638784 5165 GLP; (unpublished) Doc. No.: 541-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.12.1/01 Submitted with the PT8 BPD dossier	XXXX	2003	ARCH letter to SCC - Health data (Cholinesterase levels - Rocherster) Source: XXXX Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 574-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A6.12.1/02 Submitted with the PT8 BPD dossier	Anonymous	2001	Medical surveillance program - Carbamates - IPBC Source: XXXX Report No.: 5.13 Not GLP; (unpublished) Doc. No.: 574-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A6.12.3/01 Submitted with the PT8 BPD dossier	Ulfvarson, U. Alexandersson, R. Dahlqvist, M. Ekholm, U. Bergström, B. Scullman, J.	1992	Temporary health effects from exposure to water-borne paints Source: Scand J Work Environ Health 1992;18:376-87 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-013	No	N.R.
A6.12.5/01 Submitted with the PT8 BPD dossier	Anonymous	2003	Material safety data sheet - Omacide IPBC 100 (According to 91/155 EC) Source: Arch Chemicals B. V. Swords / Ireland Report No.: Not applicable Not GLP; (unpublished) Doc. No.: 953-007	No	ARCH Chemicals

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A6.12.6/01 Submitted with the PT8 BPD dossier	Bryld, L.E. Agner, R. Rastogi, S.C.	1997	Iodopropynyl butylcarbamate: a new contact allergen Source: Contact Dermatitis vol. 36, pp. 156-158, 1997 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-003	No	N.R.
A6.12.6/02 Submitted with the PT8 BPD dossier	Pazzaglia, M. Tosti, A.	1999	Short Communications - Allergic contact dermatitis from 3-iodo-2-propynyl-butylcarbamate in a cosmetic cream Source: Contact Dermatitis, Vol. 41, pp. 290, 1999 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-006	No	N.R.
A6.12.6/03 Submitted with the PT8 BPD dossier	Majoie, I.M. van Ginkel, J.W.	2000	The biocide iodopropynyl butylcarbamate (IPBC) as an allergen in cutting oils Source: Contact dermatitis, 2000, Vol. 43 p. 238 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-007	No	N.R.
A6.12.6/04 Submitted with the PT8 BPD dossier	Bryld, L.E. Agner, T. Menné, T.	2001	Allergic contact dermatitis from 3-iodo-2-propynyl-butylcarbamate (IPBC) - an update Source: Contact dermatitis, 2001, Vol. 44, pp. 276-278 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-009	No	N.R.
A6.12.6/05 Submitted with the PT8 BPD dossier	Schnuch, A. Geier, J. Brasch, J. Uter, W.	2001	The preservative iodopropynyl butylcarbamate: frequency of allergic reactions and diagnostic considerations Source: Contact Dermatitis 2002, 46, 153-156 Report No.: ISSN 0105-1873 Not GLP; (published) Doc. No.: 592-010	No	N.R.
A6.12.6/06 Submitted with the PT8 BPD dossier	Jensen, C.D. Thormann, J. Andersen, K.E.	2003	Airborne allergic contact dermatitis from 3-Iodo-2-Propynyl-Butylcarbamate at a paint factory Source: Contact dermatitis 2003, 48, 155-157 Report No.: ISSN 0105-1873 Not GLP; (published) Doc. No.: 592-011	No	N.R.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A6.12.6/07 Submitted with the PT8 BPD dossier	Brasch, J. Schnuch, A. Geier, J. Aberer, W. Uter, W.	2004	Contact Dermatitis and Allergy Iodopropynylbutyl carbamate 0-2% is suggested for patch testing of patients with eczema possibly related to preservatives Source: British Journal of Dermatology 2004, Vol. 151, page 608-615, © 2004 British Association of Dermatologists Report No.: Not applicable Not GLP; (published) Doc. No.: 592-017	No	N.R.
A7.1.1.1.1/01 Submitted with the PT8 BPD dossier	Jungheim	2001	Preventol MP 100 - Abiotic degradation Source: Bayer AG, Leverkusen, Germany Report No.: N 00/0070/05 LEV GLP; (unpublished) Doc. No.: 711-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A7.1.1.1.1/02 Submitted with the PT8 BPD dossier	Reynolds, J.L.	1994	Hydrolysis of 14C-3-iodo-2-propynyl-n-butylcarbamate (14C-IPBC) Source: Xenobiotioc Labs Report No.: XBL 94051 RPT00201 GLP; (unpublished) Doc. No.: 711-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A7.1.1.1.2/01 Submitted with the PT8 BPD dossier	Lee, D.-H. Tsunoda, K. Takahashi, M.	1991	Photostability of organoiodine wood preservatives I. Progressive degradation and loss in fungal inhibition rate through photoirradiation Source: Mokuzai Gakkaishi, Vol. 37, No. 1, p. 76-81 (1991) Report No.: Vol. 37, No. 1 Not GLP; (published) Doc. No.: 792-005	No	N.R.
A7.1.1.1.2/02 Submitted with the PT8 BPD dossier	Lee, D.-H. Tsunoda, K. Takahashi, M.	1991	Photostability of organoiodine wood preservatives II. The photolytic process of preservatives Source: Mokuzai Gakkaishi, Vol. 37, No. 3, p. 261-265 (1991) Report No.: Vol. 37, No. 3 Not GLP; (published) Doc. No.: 792-004	No	N.R.
A7.1.1.1.2/03 Submitted with the PT8 BPD dossier	Phaff, R.	2005	AQUEOUS PHOTOLYSIS OF IPBC AND DETERMINATION OF THE QUANTUM YIELD Source: Research and Consulting Company, Itingen, Switzerland Report No.: 856160 GLP; (unpublished) Doc. No.: 712-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, DOW, ISP, LANXESS, TROY)

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A7.1.1.2.1/01 Submitted with the PT8 BPD dossier	Grützner, I.	2002	Ready biodegradability of IPBC in a manometric respirometry test Source: Research and Consulting Company, Itingen, Switzerland Report No.: TC-1261 831172 GLP; (unpublished) Doc. No.: 713-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A7.1.1.2.2/01 Submitted with the PT8 BPD dossier	Seyfried, B.	2004	Inherent Biodegradability of IPBC in a modified "Zahn-Wellens /EMPA Test" Source: Research and Consulting Company, Itingen, Switzerland Report No.: 851399 GLP; (unpublished) Doc. No.: 713-007	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, DOW, LANXESS, TROY)
A7.1.2.2.2/01 Submitted with the PT8 BPD dossier	Blumhorst, M.R.	1992	Anaerobic aquatic metabolism study of P-100 Source: EPL Bio Analytical Services, USA Report No.: TC-0315 147-003 GLP; (unpublished) Doc. No.: 715-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A7.1.3/01 Submitted with the PT8 BPD dossier	Schneider, U.	2002	Estimation of the adsorption coefficient on soil and on sewage sludge using HPLC Source: Infracor Chemistry Services Report No.: AN-ASB 0203 GLP; (unpublished) Doc. No.: 731-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	DOW Benelux B.V.
A7.1.3/02 Submitted with the PT8 BPD dossier	Blumhorst, M.R.	1990	Adsorption/Desorption studies - batch equilibrium for P-100 Source: EPL Bio Analytical Services, USA Report No.: TC-0312 147-002 GLP; (unpublished) Doc. No.: 731-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A7.2.1/01 Submitted with the PT8 BPD dossier	Blumhorst, M.R.	1992	Aerobic soil metabolism study of P-100 Source: EPL Bio Analytical Services, USA Report No.: TC-0307 147-004 GLP; (unpublished) Doc. No.: 722-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A7.2.3.1/01 Submitted with the PT8 BPD dossier	Schimmel-pfennig, H.	2004	Estimation of the Koc of the IPBC degradation product PBC using the PCKOC programm (v1.66) Source: Scientific Consulting Company, Wendelsheim, Germany Report No.: 824-006 Not GLP; (unpublished) Doc. No.: 731-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, DOW, ISP, LANXESS, TROY)

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A7.3.1/01 Submitted with the PT6 BPD dossier	Görg, J. Glöckner, T.	2007	Estimation of the Atmospheric Residence Time of IPBC using the Atkinson Method - IPBC Source: Scientific Consulting Company, Wendelsheim, Germany Report No.: 824-014 743-002 Atkinson Not GLP; (unpublished) Doc. No.: 743-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, DOW, ISP, LANXESS, TROY)
A7.4.1.1/01 Submitted with the PT8 BPD dossier	XXXX	1994	Acute toxicity of Omacide IPBC to the fathead minnow (Pimephales promelas) Source: XXXX Report No.: 293- XXXX GLP; (unpublished) Doc. No.: 821-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A7.4.1.1/02 Submitted with the PT8 BPD dossier	XXXX	1991	TROYSAN Polyphase P-100 - Acute toxicity to sheepshead minnow (Cyprinodon variegatus) under flow-through conditions Source: XXXX Report No.: TC-0299 91-10-3983 12166.0791.6103.505 GLP; (unpublished) Doc. No.: 821-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A7.4.1.1/03 Submitted with the PT8 BPD dossier	XXXX	1990	TROYSAN Polyphase P-100 - Acute toxicity to bluegill sunfish (Lepomis macrochirus) under flow-through conditions Source: XXXX Report No.: TC-0289 90-04-3300 12166.0789.6100.105 GLP; (unpublished) Doc. No.: 821-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A7.4.1.1/04 Submitted with the PT8 BPD dossier	XXXX	2001	Preventol MP 100 - Acute Fish Toxicity Source: XXXX Report No.: 1025 A/00 XXXX GLP; (unpublished) Doc. No.: 821-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A7.4.1.1/05 Submitted with the PT8 BPD dossier	XXXX	1994	Acute toxicity of Omacide IPBC to the rainbow trout, Oncorhynchus mykiss Source: XXXX Report No.: 294- XXXX GLP; (unpublished) Doc. No.: 821-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A7.4.1.1/05b Submitted with the PT8 BPD dossier	XXXX	1990	TROYSAN Polyphase P-100 - Acute toxicity to rainbow trout (Oncorhynchus mykiss) under flow-through conditions Source: XXXX Report No.: TC-0290 90-03-3261 12166.0789.6100.108 GLP; (unpublished) Doc. No.: 821-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A7.4.1.1/06 Submitted with the PT8 BPD dossier	XXXX	1992	(Propargyl Butyl Carbamate) - Acute Toxicity to rainbow trout (Oncorhynchus mykiss) under flow-through condition Source: XXXX Report No.: TC-0305 XXXX No. 92-3-4146 12166.0991.6108.108 GLP; (unpublished) Doc. No.: 821-007	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A7.4.1.2/01 Submitted with the PT8 BPD dossier	Boeri, R.L. Magazu, J.P. Ward, T.J.	1994	Acute toxicity of Omacide IPBC to the daphnid, Daphnia magna Source: T.R. Wilbury Laboratory, Massachusetts Report No.: 292-OL GLP; (unpublished) Doc. No.: 822-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A7.4.1.2/02 Submitted with the PT8 BPD dossier	Putt, A.E.	1992	(Propargyl Butyl Carbamate) - Acute Toxicity to daphnids (Daphnia magna) under flow-through conditions Source: Springborn Laboratories Massachusetts, USA Report No.: TC-0304 SLI No. 92-2-4122 12166.0991.6109.115 GLP; (unpublished) Doc. No.: 822-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A7.4.1.3/01 Submitted with the PT8 BPD dossier	Peither, A.	2001	Toxicity of Polyphase P-100 to Scenedesmus subspicatus in a 72-hour algal growth inhibition test – (Included the Analytical Report – Determination of the Concentrations of the test item in test medium) Source: Research and Consulting Company, Itingen, Switzerland Report No.: 790413 790424 TC0072 GLP; (unpublished) Doc. No.: 823-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A7.4.1.3/02 Submitted with the PT8 BPD dossier	Boeri, R.L. Magazu, J.P. Ward, T.J.	1994	Growth and reproduction test with Omacide IPBC and the freshwater alga, Selenastrum capricornutum Source: T.R. Wilbury Laboratory, Massachusetts Report No.: 295-OL GLP; (unpublished) Doc. No.: 823-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A7.4.1.3/03 Submitted with the PT8 BPD dossier	Ward, T.J. Boeri, R.L. Magazu, J.P.	1997	Growth and Reproduction Toxicity test with Propargal Butyl Carbamate and the Freshwater Alga, Selenastrum capricornutum Source: T.R. Wilbury Laboratory, Massachusetts Report No.: TC0553 1115-TR GLP; (unpublished) Doc. No.: 823-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A7.4.1.4/01 Submitted with the PT8 BPD dossier	Müller	2000	Preventol MP 100 – Toxicity to bacteria Source: Bayer AG, Leverkusen, Germany Report No.: 1025 A/00 B GLP; (unpublished) Doc. No.: 842-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A7.4.1.4/02 Submitted with the PT8 BPD dossier	Mead, C.	2002	IPBC – Acute toxicity to bacteria (Pseudomonas putida) Source: Safepharm Laboratories Limited, Derby Report No.: 1597/006 GLP; (unpublished) Doc. No.: 842-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A7.4.3.2/01 Submitted with the PT8 BPD dossier	XXXX	1992	TROYSAN Polyphase P-100 – Toxicity to fathead minnow (Pimephales promelas) embryos and larvae Source: XXXX Report No.: TC-0301 92-1-4057 12166.0791.6104.120 GLP; (unpublished) Doc. No.: 826-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A7.4.3.4/01 Submitted with the PT8 BPD dossier	Ward, G.S.	1991	TROYSAN Polyphase P-100 – Chronic toxicity to the water flea, Daphnia magna, under flow-through test conditions Source: Toxicon Environmental Sciences Report No.: TC-0294 J9009031b GLP; (unpublished) Doc. No.: 827-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A7.5.1.1/01 Submitted with the PT8 BPD dossier	Reis, K.-H.	2004	Effects of IPBC Technical on the Activity of the Soil Microflora in the Laboratory Source: Ibacon GmbH, Rossdorf, Germany Report No.: 17921080 GLP; (unpublished) Doc. No.: 841-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, DOW, LANXESS, TROY)

Section No./ Reference No.	Author(s)	Year	Title Source Report GLP; Doc. No. (laboratory) No. (un)published	Data protection	Owner
A7.5.1.2/01 Submitted with the PT8 BPD dossier	Lührs, U.	2004	Acute toxicity (14 Days) of IPBC technical to the earthworm Eisenia fetida in artificial soil Source: Ibacon GmbH, Rossdorf, Germany Report No.: 17922021 GLP; (unpublished) Doc. No.: 833-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, DOW. LANXESS, TROY)
A7.5.1.3/01 Submitted with the PT8 BPD dossier	Spatz, B.	2004	Effects of IPBC Technical on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Test Source: Ibacon GmbH, Rossdorf, Germany Report No.: 17923084 GLP; (unpublished) Doc. No.: 851-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, DOW, LANXESS, TROY)