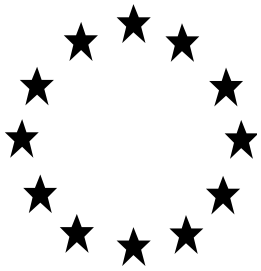
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



3-iodo-2-propynyl butyl carbamate (IPBC)

Product-type 13
(Working or cutting fluid preservatives)

January 2015

Denmark

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of the active substance 3-iodo-2-propynyl butyl carbamate (IPBC) as product-type 13 (working or cutting fluid preservatives), carried out in the context of the work programme for the review of existing active substances provided for in Article 89 of Regulation (EU) No 528/2012, with a view to the possible approval of this substance.

3-iodo-2-propynyl butyl carbamate (IPBC) (CAS no. 55406-53-6) was notified as an existing active substance, by the European Union IPBC Task Force (Arch Chemicals, Dow Benelux B.V., ISP Switzerland GmbH, Lanxess Deutschland GmbH, Troy Corp), hereafter referred to as the applicant, in product-type 13.

Commission Regulation (EC) No 1451/2007 of 4 December 2007[1] lays down the detailed rules for the evaluation of dossiers and for the decision-making process.

In accordance with the provisions of Article 7(1) of that Regulation, Denmark was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for IBPC as an active substance in Product Type 13 was 31 July 2007, in accordance with Article 9 of Regulation (EC) No 1451/2007.

On 31 July 2007, DK competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 29 January 2008.

On 23 August 2013, the Rapporteur Member State submitted to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Agency. Revisions agreed upon were presented at the Biocidal Products Committee and its Working Groups meetings and the competent authority report was amended accordingly.

1.2. Purpose of the assessment report

The aim of the assessment report is to support the opinion of the Biocidal Products Committee and a decision on the approval of IPBC for product-type 13, and, should it be approved, to facilitate the authorisation of individual biocidal products. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available from the Agency web-site, shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the

[1] Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

benefit of another applicant, unless access to these data for that purpose has been granted to that applicant.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

Identity

IPBC, CAS No. 55406-53-6, is a fungicide produced and/or supplied by Arch Chemicals, Dow Benelux B.V., ISP Switzerland GmbH, Lanxess Deutschland GmbH, Troy Corp. at/from sites in and out of Europe. Analysis of five technical grade batches which are representative of the current manufacturing process demonstrated a mean purity of ≥ 98% w/w in compliance with European Union IPBC Task Force (Arch Chemicals, Dow Benelux B.V., ISP Switzerland GmbH, Lanxess Deutschland GmbH, Troy Corp.) specifications. All impurities above the level of 1 g/kg have been fully identified and the corresponding methods of analysis have been developed. The main identification characteristics were given in a confidential document (please see the IPBC dossier for PT 8 and 6). The active substance must be technically equivalent to the specifications given. None of the manufacturing impurities are considered to be of potential concern.

Physical and chemical properties

IPBC technical is a yellowish crystalline powder with a faint odour of iodine and a melting point of 65.8 – 66.5°C. Its relative density is 1.71 at 20°C.

The vapour pressure is found to be 2.36-4.5 x 10-3 Pa at 25°C. The water solubility of IPBC technical is 0.168 g/L (pH 7) at 20°C.

IPBC is very soluble in methanol (>1000 g/L) and other organic solvents. Its octanol/water partition coefficient (log P_{OW}) is 2.81 at 25°C.

The substance is stable at room temperature and is stable at 54°C for 14 days. IPBC is not highly flammable. It has no pyrophoric property and it does not undergo spontaneous combustion. IPBC is not explosive.

The recommended container material for IPBC is protected steel drums.

Methods of analysis

The identification and quantification of IPBC as manufactured is performed using HPLC-UV and GC-FID. Methods of analysis for residues are HPLC-MS/MS.

Methods were developed to analyse residues in soil, water, body fluids and tissues with the respective limits of quantification of 10 µg/kg of soil, 0.1 µg/L of water, 0.05 mg/L of body fluids and 0.1 mg/L of tissues.

Methods for the analysis of residues in air were not necessary because IPBC is not volatile and spray applications only involve non-respirable particles.

An analytical method for the determination of residues of IPBC in/on food or feedstuffs is not required because the active substance is not used in a manner that may cause direct contact with food or feedstuffs.

2.1.2. Intended Uses and Efficacy

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organism(s) and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious.

The biocidal products produced by the TF members for metalworking fluid preservation have typical concentrations in the range of 10 to 40% IPBC. In end-use products (metalworking fluids), IPBC is contained at concentrations ranging from 0.005 to 0.1% w/w.

The results of the laboratory based simulation studies demonstrate that IPBC is effective against fungi (mixture of unspecified and defined fungi) in commonly used metalworking fluids at concentrations in the range of 0.0075% - 0.015% w/w.

Specific efficacy data will be provided for the respective products, concentrations and use at the product authorization stage.

When the active substance is added to the concentrate to preserve the final emulsificable and water soluble solution, the dose of the biocide should be in accordance to the dilution instructions of the concerning metalworking fluid concentrate in order to reach an efficacious concentration in the final solution.

In addition, in order to facilitate the work of Member States in granting or reviewing after authorisations, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

2.1.3. Classification and Labelling

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

Classification		
Class of danger	T N	Toxic Dangerous for the environment
R phrases	R22 R23	Harmful if swallowed. Toxic by inhalation
	R41 R48/23 R43 R50	Risk of serious damage to the eye Danger of serious damage to health by prolonged exposure through inhalation May cause sensitization by skin contact Very toxic to aquatic organisms.
S phrases	S1 S2 S23 S24 S26 37/39 S45 S63	Keep locked up. Keep out of the reach of children Do not breathe vapour/spray Avoid contact with skin In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable gloves and eye/face protection In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). In case of accident by inhalation: remove casualty to fresh air and keep at rest

Harmonised classification based on Regulation EC 1272/2008:

Signal Word	Danger	
Pictograms	GHS05, GHS06, GHS08, GHS09	
Hazard class and category code(s)	Acute Tox 3 Eye Dam. 1 Acute Tox 4 Skin Sens. 1 STOT RE 1 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 for acute and 1 for 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).

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification

IPBC is of moderate acute toxicity by the oral route and of low toxicity by the dermal route. IPBC is classified toxic by inhalation. The substance is not irritating to skin but is a severe eye irritant and a skin sensitizer.

In the short term studies the liver and kidney were the main target organs. Repeated exposure by inhalation of solid IPBC resulted in histopathological findings (hyperplasia or squamous metaplasia and necrosis of the underlying cartilage) in the central region of the larynx and was regarded as a local and not systemic effect. IPBC was neither carcinogenic, neurotoxic or genotoxic. IPBC is not toxic to reproduction or a developmental toxicant.

2.2.1.2. Effects assessment

IPBC was completely and readily absorbed via the oral route (<90%). Following absorption, the substance was widely distributed with no trend for bioaccumulation observed. IPBC was extensively metabolised with the major metabolites being the two distereomeric conformers of propargyl-N-acetic acid carbamate. Glucuronidation appeared to be the main secondary metabolism pathway. The majority of the administered radioactivity was excreted via urine (57.3% to 70.7%) with faeces being a minor route (4.4% to 7.4%); radiolabelled carbon dioxide constituted between 18.4 to 24.2% of the administered dose. There were no differences between sexes or applied doses detectable.

For IPBC, an in vitro study with human skin gave the following dermal absorption values (including skin residues): 30 % for the solvent based formulations C containing 0.6 % IPBC, 10 % for B containing 2.3 % IPBC and 1.6 % for A containing 17.1 % IPBC

Dermal absorption values used in the applications for product authorisation should be justified, if available by the submission of specific dermal absorption data on the product, or by read-across to existing data if scientifically justified, or by using the default values from the Scientific opinion of EFSA.

In **acute toxicity studies**, IPBC was found to be of moderate acute toxicity by the oral route and of low acute toxicity by the dermal routes of exposure but has high acute toxicity by the inhalation route. The data support classification of IPBC for acute toxicity by the inhalation route.

IPBC is not a skin irritant, but does exhibit the potential to produce severe eye irritation. In animal studies, IPBC met the criteria for classification as a severe eye irritant.

Positive findings from guinea pig sensitisation studies (GPMTs) indicate that IPBC has skin sensitisation potential.

Following repeated oral administration of IPBC post-dose salivation was observed immediately after dosing by gavage from 30 mg/kg bw/day, but not when IPBC was administered via the diet. Food consumption was reduced from 80 mg/kg bw/day (dietary, gavage) and body weights and/or body weight gains from 40 mg/kg bw/day (dietary) or 80 mg/kg bw/day (gavage). Brain and RBC cholinesterase activities were not reduced up to and including the highest dose levels administered. Local erosions, ulceration, and/or inflammation of the stomach (forestomach and/or glandular stomach) were observed from about 20 to 30 mg/kg bw/day (dietary, gavage). Increased liver weights, sometimes accompanied by hepatocellular changes, and increased kidney weight (females only) were observed from 30 to 40 mg/kg bw/day. Increased incidence in foamy macrophage

aggregates was noted in the lungs of male rats from 40 mg/kg bw/day in the 2-year study. In the 78-week mice study, an increased incidence in enlarged thyroids accompanied by foci of small vacuolated cells most likely of follicular origin and general follicular enlargement was noted at 150 mg/kg bw/day; the toxicological significance of these findings in thyroids remains unclear.

Following repeated dermal administration to rats dermal irritation persisting throughout the treatment period, and hyperkeratosis and ulceration was observed at 500 mg/kg bw/day; at 200 mg/kg bw/day, mild hyperkeratosis. No adverse systemic effects were observed.

Following repeated inhalation to rats decreased RBC cholinesterase activity was observed in females at 6.7 mg/m^3 *(after 2 weeks but not at study termination)* and decreased brain cholinesterase activities in females and in males at 6.7 mg/m^3. The finding is of unclear relevance since no clear dose-relationship was observed (small decrease for a large change in dose) and the normal variation seems to be wide. Results indicated that IPBC was not neurotoxic. This was also supported by the acute and 90-day neurotoxicity and 104 weeks studies in rats and 78 weeks mice study (all investigating RBC and brain cholinesterase inhibition). Histopathological findings were epithelial hyperplasia in the central region of the larynx, hyperplasia or squamous metaplasia in the ventrolateral region of the larynx, and necrosis of the underlying cartilage of the larynx at 6,7 mg/m^3 (NOAEC 1 mg/m^3). The effects on larynx are considered as a local and not a systemic effect.

IPBC was not neurotoxic when administered via the oral route.

The weight of evidence from the available well-conducted *in vitro* and *in vivo* genotoxicity studies indicates that IPBC is not a genotoxic substance.

IPBC was not carcinogenic in rats and mice up to and including the highest dose levels tested (80 and 150 mg/kg bw/day for rats and mice, respectively).

In experimental animal studies IPBC did not affect fertility and did not cause developmental toxicity. The evidence suggests that this substance does not possess significant potential with respect to toxicity to reproduction.

Reference values for the risk assessment (AEL)

Two different values will be used as basis for the risk characterisation of systemic effects:

The $AEL_{long\text{-}term}$ was derived from the 104 weeks chronic toxicity/carcinogenicity study with rats with NOAEL 20 mg/kg bw/day based on reduced mean body weight and body weight gain in both sexes and increased incidence of histopathological changes in stomach, forestomach and salivary glands.

An uncertainty factor of 100 will be applied to the NOAEL for a 10-fold factor for interspecies variability and a 10-fold factor for intraspecies variability. As absorption by the oral route was found to be close to 100%, no correction for absorption from the gastro-intestinal tract has been made in the AEL setting.

$AEL_{long\text{-}term}$= 20 mg/kg bw/day / 100 = 0.2 mg/kg bw/day

As IPBC is not toxic to reproduction or a developmental toxicant the most relevant study to be chosen as a basis for setting the AEL_{acute} and $AEL_{medium\text{-}term}$ seems to be the 3 months gavage study in rats which has the lowest relevant NOAEL (~35 mg/kg bw/day) based on reduced body weight and body weight gain, increased absolute and relative kidney and liver weight and increased iron concentration.

AEL_{acute} and $AEL_{medium\text{-}term}$ = 35 mg/kg bw/day / 100 = 0.35 mg/kg bw/day

For details on the AEL deduction, please refer to Document IIA, chapter 3.11.

2.2.1.3. Systemic exposure assessment and Risk characterisation

In line with the TNsG on Human Exposure to Biocidal Products (2002), the DK CA has carried out for the model product (and end use concentrations) and its specified uses, an exposure assessment for human health based on a tiered approach. Each exposure assessment started with a Tier I using worst-case assumptions (e.g. assuming no personal protective equipment is worn). If an unacceptable risk is identified for a particular exposure scenario, then a further refinement of the exposure/risk assessment was carried out using additional parameters (e.g. additional PPE etc.) in Tier II.

Industrial /professional application

Exposure during industrial/professional application of IPBC products is possible during mixing and loading (metalworking fluid dilution, sump maintenance), tool setting and other tasks in the workshop (tool setting, dismantling of tool setting, handling work pieces) and metalworking. The results of the exposure assessment are displayed in Table 1-1. Assuming concentrations of IPBC in the range of 10 to 40 % and pre-solutions of 0.2-4 %, exposure during mixing and loading is between 0.02526 to 0.1090 mg/kg bw/day when no gloves are worn. Considering the use of gloves the exposure is reduced to 0.00026 and 0.0024 mg/kg bw/day. These exposure figures are far below the long term AEL of 0.2 mg/kg bw/day. The MOE is above 183 when no gloves are used and 8357 when wearing gloves. Thus, the risk for operators during mixing and loading is considered to be acceptable.

Metalworking results in IPBC exposures equivalent to 5.48% of AEL to 109.53% of AEL (in use concentrations 0.005-0.1% IPBC) in Tier I with the use of the conservative defaults values for hand exposure (no PPE).

In Tier II also calculated with the conservative defaults values for hand exposure this time with PPE, but only coated coverall, still no gloves during metal working resulted in IPBC exposures equivalent to 4.1% of AEL to 81.93% of AEL (in use concentrations 0.005-0.1% IPBC).

The same calculations were performed this time by using the measured data (75^{th} percentile) for hand exposure from the Henriks-Eckerman study and with the same approach regarding no PPE in Tier I and in Tier II coated coverall but no gloves. These calculations resulted in a lower percentage of the AEL (which can be seen in Table 1-1).

Tool setting and other task in the workshop result in an exposure of 0.00972 to 0.1855 mg/kg bw/day when no PPE is taken into account (Tier I) and 0.0087 to 0.1739 mg/kg bw/day when no gloves are worn but considering a coated coverall and of 0.001 to 0.02 mg/kg bw/day when wearing gloves and a coated coverall (concentration 0.005-0.1 %, (Table 1-1). The exposure accounts for a maximum of 92.73 % (Tier I) and 86.97 % (Tier 2) of the AEL for long-term exposures of 0.2 mg/kg bw/day when gloves are not worn but considering a coated coverall and 10.02 % of the AEL when wearing gloves and a coated coverall. The MOE is above 108 when no PPE is taken into account and 115 when no gloves are used but wearing a coated coverall and 998 when wearing gloves and a coated coverall. Thus, the risk for operators during tool setting and other task in the workshop is considered to be acceptable.

The mixing and loading, application and post-application tasks could potentially occur on

the same day. Therefore combined exposure was considered for all tasks.

The combined exposure during the use of MWF was calculated considering exposures obtained during mixing and loading of the highest concentration of 40 % IPBC, during tool setting and other tasks in the workshop as well as during metalworking taking into account either a conservative approach or by using actual hand exposure data from a human exposure data for the derivation of the default value for potential hand exposure.

The combined exposure during mixing and loading, metalworking and tool setting during the use of MWF leads to unacceptable risks under worst case assumptions when no gloves are worn. However, when gloves and coated coveralls are worn for all tasks other than metalworking, the combined exposure scenario shows that the risks are acceptable.

In accordance with the Scientific Opinion of EFSA a default dermal penetration value of 75% has been considered in the exposure assessment for formulations containing < 0.5% of the active substance (EFSA Journal 2012;10(4):2665).

Table 2-1 Primary exposure industrial/professional use

Exposure scenario Intended use (MG/PT)	PPE	Concentration [% IPBC]	Exposure			% AEL AEL long term 0.2 mg/kg bw/day	MOE
			Inhalation	Dermal	Total		
			[mg/day]		[mg/kg bw/day]		
Mixing and loading (metalworking fluid dilution, sump maintenance)	Normal work clothing, bare hands	0.2	0.0004	1.52	0.02526	12.63	792
		0.5	0.001	3.79	0.06314	31.57	317
		2.3	0.005	2.323	0.0388	19.4	516
		17	0.034	2.75	0.0463	23.17	432
		30	0.059	4.848	0.0818	40.89	245
		40	0.079	6.464	0.109	54.52	183
	Gloves, normal work clothing	0.2	0.0004	0.0152	0.00026	0.13	77196
		0.5	0.001	0.0379	0.00065	0.32	30878
		2.3	0.005	0.02323	0.0005	0.23	43212
		17	0.034	0.02747	0.001	0.51	19662
		30	0.059	0.04848	0.0018	0.90	11142
		40	0.079	0.06464	0.0024	1.20	8357

Exposure scenario Intended use (MG/PT)	PPE	Concentration [% IPBC]	Exposure			% AEL $AEL_{long\ term}$ 0.2 mg/kg bw/day	MOE
			Inhalation	Dermal	Total		
			[mg/day]		[mg/kg bw/day]		
Metalworking	1) Tier 1 Conservative approach, No PPE	0.005	0.0002	0.6570	0.01095	5.48	1826
		0.1	0.0033	13.14	0.2191	109.53	91
	1) Tier 2 Conservative approach, Bare hands, coated coverall	0.005	0.0002	0.4914	0.00819	4.1	2441
		0.1	0.0033	9.8280	0.1639	81.93	122
	2) Tier 1 Considering Henriks-Eckerman study, No PPE	0.005	0.0002	0.2925	0.00488	2.44	4100
		0.1	0.0033	5.85	0.0976	48.78	205
	2) Tier 2 Considering Henriks-Eckerman study, Bare hands, coated coverall	0.005	0.0002	0.1269	0.00212	1.06	9444
		0.1	0.0033	2.5380	0.0424	21.18	472

Exposure scenario Intended use (MG/PT)	PPE	Concentration [% IPBC]	Exposure			% AEL $AEL_{long\ term}$ 0.2 mg/kg bw/day	MOE
			Inhalation	Dermal	Total		
			[mg/day]		[mg/kg bw/day]		
Tool setting and other tasks in the workshop (tool setting, dismantling of tool setting, handling work pieces)	Tier 1 No PPE	0.005	0.0002	0.5562	0.00927	4.64	2157
		0.1	0.0033	11.124	0.1855	92.73	108
	Tier 2 Coated coverall, bare hands	0.005	0.0002	0.5216	0.0087	4.35	2300
		0.1	0.0033	10.4328	0.1739	86.97	115
	Tier 2 Gloves, coated coverall	0.005	0.0002	0.0599	0.001	0.5	19965
		0.1	0.0033	1.1988	0.02	10.02	998
Combined exposure during the use of MWF: Conservative approach for metalworking tasks Mixing and Loading (worst case) + Metalworking (conservative approach) + Tool setting and other tasks	Tier 1 No PPE	M/L: 40 / In-use: 0.005	0.0794	7.6772	0.1292	64.6	155
		M/ L: 40 / In-use: 0.1	0.0856	30.728	0.5136	257	39
	Tier 2 Bare hands, coated coverall	M/L: 40 / In-use: 0.005	0.0794	7.477	0.1259	63	159
		M/ L: 40 / In-use: 0.1	0.0856	26.72	0.4468	223.38	45
	Tier 2 Gloves, coated coverall (Note: No gloves during metalworking	M/L: 40 / In-use: 0.005	0.0794	0.616	0.0116	5.8	1724
		M/ L: 40 / In-use: 0.1	0.0856	11.09	0.1863	93.1	107
Combined exposure during the use of MWF: Considering the study of	Tier 1 No PPE	M/L: 40 / In-use: 0.005	0.0794	7.3127	0.1232	61.6	162
		M/ L: 40 / In-use: 0.1	0.0856	23.438	0.3921	196	51

Exposure scenario Intended use (MG/PT)	PPE	Concentration [% IPBC]	Exposure			% AEL $AEL_{long\ term}$ 0.2 mg/kg bw/day	MOE
			Inhalation	Dermal	Total		
			[mg/day]		[mg/kg bw/day]		
Henriks-Eckerman, 2007	Tier 2 Bare hands, coated coverall	M/L: 40 / In-use: 0.005	0.0794	7.1125	0.1199	59.93	167
		M/ L: 40 / In-use: 0.1	0.0856	19.43	0.3253	163	61
Mixing and Loading (worst case) + Metalworking (Henrik-Eckerman study) + Tool setting and other tasks	Tier 2 Gloves, coated coverall (Note: No gloves during metalworking)	M/L: 40 / In-use: 0.005	0.0794	0.2514	0.0055	2.76	3636
		M/ L: 40 / In-use: 0.1	0.0856	3.80	0.0648	32.38	309

Secondary exposure

Secondary exposure is not relevant for the industrial use of IPBC in MWF as the metals are further used by professionals or in industry when the processed metals were cleaned.

Combined exposure

Adults are the only subpopulation who may reasonably experience MWF containing IPBC. In the worst case scenario of a professional who is involved in mixing and loading, tool setting and other tasks in the workshop as well as metalworking the exposure is acceptable when gloves and coated coveralls are worn for all tasks other than metalworking, the combined exposure scenario shows that the risks are acceptable.

Overall conclusion

The use of IPBC in industrial/professional applications for MWF (PT13) can be considered acceptable when appropriate PPEs are worn. The secondary exposure is not relevant. Thus the overall outcome of the risk assessment for humans, that has covered normal/representative use of the biocide product together with a realistic worst case scenario as well as the material treated with it, is that proper use, i.e. use in compliance with the conditions on the label, of IPBC is acceptable.

2.2.1.4. Risk characterisation for local effects

The model formulation must be classified with the R-phrases R41 (H318) and R43 (H317; Skin Sens. 1) due to the classification and content of the active substance as an severe eye irritant and a skin sensitizer. However it has to be remembered that the mix/load phase is fully automated and the in use concentration of the product, which is typically where the actual exposure would be, contains about 0.005%-0.1% IPBC. During metalworking where no gloves will be worn, the maximum IPBC concentration is 0.1% which is well below the threshold for a classification with respect to skin sensitisation and eye irritation (thresholds of 1% apply for both endpoints acc. to the CLP).

Due to the low vapour pressure of IPBC of 0.00234 Pa (2.34 mPa) and according to the "HEEG opinion on Assessment of Inhalation Exposure of Volatilised Biocide Active Substance" IPBC is not volatilized. Exposure from inhalation is therefore considered negligible. The concern regarding local effects arises from the effects seen on larynx in rats after repeated exposure which leads to a classification of IPBC with R48/23 (DSD) and STOT RE 1; H372 (CLP) based on the larynx effects.

However, a local exposure assessment is not required even if a worst case approach based on the R48/23 (DSD) and STOT RE 1; H372 (CLP) classification is taken. As no respiratory exposure is anticipated during application of the liquid diluted products, an exposure and risk assessment for local effects via the inhalation route is not required. However a qualitative risk assessment for local effects has been performed. It has to be emphasized that normally risk assessment for local effects are NOT performed on the active substance classifications but on the product and its resulting classification.

Only professionals in automated processes are handling products classified with STOT RE1; H372 (larynx) according to CLP (DSD T; R48/23). These products (10-40 %IPBC) are either directly mixed into the MWFs or automatically diluted to a pre-solution of 0.2 to 4 % IPBC. For professionals PPE can be prescribed. For all other uses for professionals the handling of the end products, which contains 0.005-0.1% IPBC, will not lead to classification of the end products for the larynx effect. During metal working aerosols might be generated when the MWF is in contact with fast rotating tools. However the STOT RE1 classification based on the larynx effects is not relevant since MWF (end product) will be below the classification limit for this effect. MWF contains 0.005-0.1% IPBC.

As the classification of a biocidal product with STOT RE 1; H372 is triggered by the classification limit of ≥ 10% and with STOT RE 2; H373 by the classification limit of ≥ 1% (but < 10%) local effects are not to be expected at the representative in-use concentrations of 0.005-0.1% IPBC. Therefore, a risk characterization for local effects via the inhalation route is not required as local effects can be excluded at the representative in-use concentrations.

In conclusion, a local exposure assessment is not required even if a worst case approach based on the STOT RE 1; H372 (CLP) or R48/23 (DSD) classification is taken. Consequently, as no respiratory exposure/irritation is anticipated during application of the liquid diluted products, an exposure and risk assessment for local effects via the inhalation route is not required. However a qualitative risk assessment for local effects has been performed. It has to be emphasized that normally risk assessments for local effects are NOT performed on the active substance classifications but on the product and its resulting classification.

It was decided at the Working group meeting September 2014 that an $AEC_{inhalation}$ was not needed for the representative product but instead the NOAEC of 1.16 mg/m^3 for the larynx effect should be stated in LoEP for future uses where inhalation exposure could be relevant.

A NOAEC of 1.16 mg/m^3 for the larynx effects has been identified for solid IPBC, however it is highlighted that this is not a NOAEC for the product. The relevance of this value has to be considered for the specific products (containing formulants) and the resulting classification of these.

2.2.2. Environmental Risk Assessment

2.2.2.1. Fate and distribution in the environment

IPBC is stable to hydrolysis. Direct photodegradation of IPBC in water is low and the substance may be considered photolysis stable in water.

Air will not be an environmental compartment of concern for IPBC because of the low vapour pressure of this compound. It should also be noted that the calculated DT50 of IPBC in air is only about 15 hours and IPBC is therefore not considered persistent in air.

IPBC is not readily biodegradable but is primary biodegradable according to Zahn-Wellens test. IPBC did not pass the validity criteria of the Zahn-Wellens test to be classified as inherent biodegradable because the DOD/DOC was not measured. However, the study demonstrates that IPBC is rapidly transformed into PBC (within 2 hours) in the modified Zahn-Wellens test. Therefore, it is considered in the risk assessments that IPBC is completely transferred into PBC in the STP without considering a further degradation of PBC. The biodegradation half-life in surface water is estimated to about 3.1 hour at 12 ° C. IPBC is metabolised rapidly in soil in laboratory experiments, the half-life is estimated to be 4.7 hours at 12 °C. In degradation of IPBC, the primary degradation product was propargyl butyl carbamate (PBC). PBC was found in hydrolysis, aerobic soil, and anaerobic aquatic metabolism studies. In hydrolysis, PBC was the only degradation product identified.

In soil, PBC was degraded to CO_2, bound soil residues and an unidentified metabolite. In anaerobic aquatic environments (sediment/water), PBC was degraded to 2-propenyl butyl carbamate (2-PBC) and 2 unidentified degradation products (less than 10%), CO_2 and possibly CH_4. The m etabolite 2-PBC is only formed at a percentage > 10% in the water phase under anaerobic conditions. QSAR estimation indicates a toxicity of this metabolite

which is comparable to that found for IPBC. Therefore in this case it is not considered necessary to ask for experimental ecotoxicological data for this metabolite as IPBC is not likely to undergo anaerobic degradation in any of the environmental compartments that IPBC will reach when used in PT13; however, anaerobic degradation can occur in the sewage sludge if the sludge is used in biogas production, this is not included in this evaluation.

An evaluation of the degradation products iodide and iodate released from IPBC is included in the exposure and risk assessment, however for the fate and distribution in the environment and for the effect assessment of iodide and iodate data from the Swedish first Draft CAR of iodine are used.

IPBC has a medium to high mobility potential.

The bioaccumulation potential is not significant based on a log Pow value of 2.8.

2.2.2.2. Effects assessment

The toxicity to aquatic organisms is documented by acute and long-term studies. Long-term NOEC values are available for all three trophic levels in the aquatic compartment: The lowest NOEC from the algae study of 0.0046 mg/L was taken as the basis for the PNEC derivation in water.

The PNEC for the sediment is calculated using the equilibrium method. However, the risk to the sediment is the same as that described for surface water. Therefore the risk of the sediment will not be considered further.

The toxicity to terrestrial organisms is documented by acute studies. Studies are available for tests on earthworm, terrestrial micro-organisms and terrestrial plants. The plant test with an EC_{50} of 4.92 mg/kg was taken as the basis for the terrestrial PNEC.

The following PNEC values are used in the risk assessment for IPBC:

$PNEC_{water}$ = 0.0046 mg/L / 10 = 0.0005 mg/L

$PNEC_{STP}$ = 44.00 mg/L / 100 = 0.44 mg/L

$PNEC_{soil}$ = 4.92 mg/kg dry soil/1000 = 0.005 mg/kg dry soil

PBC was identified as a relevant metabolite of IPBC in water, sediment and soil, because it was found in degradation studies at above the limit value of 10%. Due to a relative short half-life of PBC (T½ of 31.2; 31.4 and 9.5 days at 12 °C in water, sediment and soil, respectively) PBC can be regarded as a transient metabolite. In addition, the ecotoxicity of PBC is a factor of 300 – 1000 lower for fish, invertebrates and algae compared to IPBC.

The following PNEC values are used in the risk assessment for PBC:

$PNEC_{water}$ = 41.3 mg/L / 1000 = 0.0413 mg/L

$PNEC_{soil}$ = 0.149 mg/kg wet soil = 0.169 mg/kg dry soil (calculated from $PNEC_{water}$)

For the $PNEC_{STP}$ the one for IPBC is used as a worst case.

For iodine, iodide and iodate the ERA is based on the background concentrations.

A metabolite 2-PBC is formed at a percentage > 10% in the water phase; however only under anaerobic conditions. QSAR estimation indicates a toxicity of this metabolite which is comparable to that found for IPBC. Therefore in this case it is not considered necessary to ask for experimental ecotoxicological data for this metabolite.

2.2.2.3. PBT and POP assessment

A PBT assessment is carried out for IPBC and PBC according to the REACH guidance on PBT assessment.

Persistence criteria (P)

IPBC is not readily biodegradable but is primary biodegradable according to Zahn-Wellens test. In an aerobic soil degradation study, IPBC is rapidly degraded with a DT_{50} of 2.1 hour at 22 ºC (DT_{50} of 4.7 hours at 12 ºC). In a water sediment study a DT_{50} of 1.4 hour at 22 ºC (DT_{50} of 3.1 hours at 12 ºC) was found for the water phase and a DT_{50} of 2.2 hour at 22 ºC (DT_{50} of 4.9 hours at 12 ºC) was found for the sediment phase. As these half-lives are below the trigger values, the P criterion for IPBC is not fulfilled.

The degradation DT_{50} of PBC in freshwater was found to be 14.2 days at 22 ºC (DT_{50} of 31.2 days at 12 ºC), in sediment the DT_{50} value is 14.3 days at 22 ºC (DT_{50} of 31.4 days at 12 ºC) while the degradation half-live in soil of PBC is 4.3 days at 22 ºC (DT_{50} of 9.5 days at 12 ºC). As these values are below the trigger values, the P criterion for PBC is not fulfilled.

Bioaccumulation criteria (B)

The bioaccumulation potentials are not significant based on a log Pow value of 2.8 for IPBC and 1.64 for PBC which will result in bioconcentration factors (BCF) below 2000. Therefore, the B criterion is not fulfilled for either IPBC or PBC.

Toxicity criteria (T)

For IPBC the NOEC value for algae, the most sensitive aquatic species, is 0.0046 mg/l. Therefore, the T criterion is fulfilled as a chronic NOEC below 0.01 mg/L is found for IPBC. Mammalian toxicity data do not give rise to T criteria for IPBC.

For PBC mammalian toxicity data do not give rise to T criteria. For PBC no data on chronic effects are available. Therefore short-term toxicity data are compared to the trigger of 0.1 mg/L. For PBC all the short-term toxicity data are above the trigger value and a log Pow below 4.5 results in no further assessment necessary for the toxicity criteria.

Thus IPBC and PBC do not fulfil the PBT or vPvB criteria.

Therefore IPBC and PBC don’t meet the exclusion criteria as listed in Article 5(1)(e) of the BPR. Furthermore they don’t meet two of the criteria for PBT substances according to Annex XIII to Regulation (EC) No. 1907/2006. Therefore they don’t meet the criteria for candidates of substitution as listed in Article 10(1)(d) of the BPR.

As a consequence IPBC and PBC aren’t Persistent Organic Pollutants (POP), either.

The RMS considers that a comprehensive PBT assessment is not relevant in the case of iodine. The term persistence is not appropriate, since iodine is an element and not degradable.

2.2.2.4. Exposure assessment

IPBC is emitted into the environment with the waste via the facility drain from a metal working factory, disposing off MWF via the facility drain.

The Emission Scenario Document for PT13 acknowledges that the default emission to STP (equivalent to 10% of the total influent into the STP) may be unrealistic and in the ESD document itself it is already recommended to re-evaluate these default values; therefore it is reasonable to propose an alternative approach which reflects the impact of emissions from a MWF facility on a domestic STP more realistically. Therefore, the emission to the STP according to the ESD for PT 13 is only used for a Tier I assessment. A more realistic scenario is used in Tier II. The Tier II assessment is agreed to be sufficient for the approval of an active substance at EU level, when the CAR has been submitted before 1 September 2013. However at the product evaluation stage the revised ESD if available, has to be used. At the product authorisation stage, values for Fproc for the specific process in which MVF are used need also to be specified.

For a Tier I assessment the standard scenario in the EUBEES document by Eefje van der Aa and Froukje Balk (2003), "Harmonisation of Environmental Emission Scenarios Biocides: PT 13 – Metalworking fluid preservatives" is used. The Tier I assessment was performed by using two different Fproc values, an Fproc value of 0.2 (Tier Ia) and in addition an Fproc value of 0.05 (Tier Ib). In Tier II a dilution factor of 100 from the metalworking industry to the STP, a dilution factor of 100 from the STP into the river and a Fform value of 0.5 was considered as it is realised that the default suggested in the original ESD seems to be unrealistic.

As IPBC quickly degrades to PBC, iodide and iodate within the environmental compartments, PEC calculations of PBC, iodide and iodate have been performed for the environmental compartments: STP, surface water, sediment, air, soil and groundwater were relevant. It is chosen to base the risk characterisation for the STP on the concentrations in the effluent (as suggested in the TGD); IPBC degrades totally within 4 hours in a STP and IPBC will therefore not be present in the effluent.

In the evaluation of iodine released from IPBC, it is chosen to consider 100% formation of both iodide and iodate. This proposed assessment is however worst case as it is expected that much less than 100% of the different iodine species will be present. However, for calculation of soil concentrations it is assumed that the total iodine concentration in soil is transformed into 14% iodide and 100% iodate.

2.2.2.5. Risk characterisation

IPBC released directly to the facility drain

The use of IPBC as metalworking fluid preservative results in direct emissions to a STP. The requirements for acceptable risk according to the TGD on Risk Assessment are met for Tier Ia and Tier II; however a risk is identified for TIER Ib for both the STP and for surface water. A risk in the Tier I scenario is accepted as this scenario seems to be too conservative and is assumed to be unrealistic.

The risk to the sediment is the same as that described for surface water. Therefore the risk of the sediment will not be considered further.

IPBC indirectly released to soil

The requirements for acceptable risk according to the TGD on Risk Assessment are met for Tier Ia, Tier Ib and Tier II.

Considering iodide and iodate

For surface water the predicted concentrations of both iodide and iodate are within the background level for the Tier II assessment. For Tier Ia the concentrations are only slightly above the background level. Under oxic conditions iodine is mainly present as iodate. Moreover, sorption conditions would be quite different in oxic waters. As stated in the first Draft CAR for iodine, a higher sorption constant is found for oxic waters which results in lower concentrations in surface water and higher concentrations in sediment and suspended matter.

For sediment and groundwater predicted concentrations of iodide and iodate for Tier Ia and Tier II are within the background levels, which are found acceptable.

The Tier Ib assessment results in iodide and iodate concentrations which are above the background level for sediment and surface water. However, this is accepted as the Tier I scenario seems to be too conservative and is assumed to be unrealistic.

For soil, predicted concentrations for all scenarios are well within the background level which is found acceptable.

Atmosphere and groundwater

Direct exposure to air from the described use of IPBC in PT13 is considered to be low. In addition, the vapour pressure of IPBC is low and the calculated half life in air is short (15 h). PBC might reach the air compartment due to releases from the STP. The highest annual average PEC in air for PBC was calculated to be 1.5 x 10-6 mg/m^3, 6.75 x 10-6 mg/m^3 and 3.6 x 10-7 mg/m^3 for Tier Ia, Tier Ib and Tier II, respectively. Consequently, air is not an environmental compartment of concern for IPBC or PBC. Exposure to air for iodide and iodate is considered to be low, as the compounds are assumed not to be volatile.

By using the FOCUS model PEARL it could be shown that IPBC and PBC do not leach to groundwater from the soil surface, thus posing no risk to the groundwater compartment.

The groundwater assessment for iodide and iodate calculated according to the "TGD on Risk Assessment" show that iodide and iodate do not pose a risk to the groundwater for the Tier Ia and Tier II assessment. In the Tier Ib assessment only the iodate concentration are above the background level. However, the pore water concentration calculated according to the "TGD on Risk Assessment" is a worst case approach and it is realistic to assume that the PEARL calculation would result in considerably lower PEC_{gw} values. Therefore it can be concluded that the risk to groundwater is acceptable for Tier Ia, Tier Ib and Tier II.

2.2.3. Assessment of endocrine disruptor properties

IPBC and PBC are not included in the EU list of potential endocrine disruptors (COM DG ENV, 2000).

IPBC and PBC have not been found on the Endocrine disruptor website of the European Commission: Annex 13 (List of 146 substances with endocrine disruption categorizations

prepared in the Expert meeting) and 15 (List of 66 Category 1 substances with categorisation high, medium or low exposure concern).

IPBC and PBC are not covered by the interim criteria described in Article 5.3 in BPR.

Conclusion is that neither IPBC nor PBC has endocrine disruptor properties.

2.3. Overall conclusions

The outcome of the assessment for IPBC in product-type 13 is specified in the BPC opinion following discussions at the 8th meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

2.4. List of endpoints

The most important endpoints, as identified during the evaluation process, are listed in Appendix I.

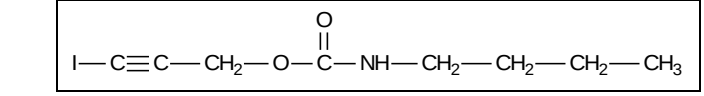
Appendix I: List of endpoints

Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling

Active substance (ISO Common Name)	IPBC, 3-Iodo-2-propynyl butyl carbamate
Function (e.g. fungicide)	Fungicide

Rapporteur Member State	Denmark

Identity (Annex IIA, point II.)

Chemical name (IUPAC)	3-Iodo-2-propynyl butyl carbamate
Chemical name (CA)	3-Iodo-2-propynyl butyl carbamate
CAS No	55406-53-6
EC No	259-627-5
Other substance No.	Not relevant
Minimum purity of the active substance as manufactured (g/kg or g/l)	980 g/kg
Identity of relevant impurities and additives (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	None
Molecular formula	$C_8H_{12}INO_2$
Molecular mass	281.1 g/mol
Structural formula	

Physical and chemical properties (Annex IIA, point III)

Melting point (state purity)	65.8 – 66.5 °C (≥ 98.8 %)
Boiling point (state purity)	No boiling point (≥ 98.8 %), decomposes
Temperature of decomposition	> 85 °C
Appearance (state purity)	Technical ≈ 98%: crystalline slightly yellow solid with a faint odour of iodine Pure 99.6%: white needles
Relative density (state purity)	1.714 (98.8%)
Surface tension	69.1 mN/m at 158 mg/L
Vapour pressure (in Pa, state temperature)	2.36-4.5 $\times 10^{-3}$ Pa (at 25 °C)
Henry's law constant (Pa m^3 mol^{-1})	3.38-6.45 $\times 10^{-3}$ Pa $\times$ m^3 $\times$ mol^{-1} (at 25 °C)
Solubility in water (g/l or mg/l, state temperature)	pH___4___: 182 mg/L (20°C)
	pH___7___: 168 mg/L (20°C)
	pH___9___: 176 mg/L (20°C)
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	3.5 g/L for heptane 3.6 g/L for petroleum ether 281 g/L for ethyl acetate 150 g/L for octanol > 1000 g/L for methanol
	all at 20 °C
Stability in organic solvents used in biocidal products including relevant breakdown products (IIIA, point III.2)	Stable in octanol, heptane and ethyl acetate for 96 h, storage at ambient conditions Stable in octanol, petroleum ether and methanol for 9 days when stored at 25 °C
Partition coefficient (log P_{OW}) (state temperature)	2.81 (25°C) Effect of pH is not relevant; IPBC is neither an acid nor a base. pH___5___:
	pH___9___:
	pH___7___:
Hydrolytic stability (DT_{50}) (state pH and temperature) (point VII.7.6.2.1)	pH 4: 267 days (25°C)
	pH 7: 248 days (25°C)
	pH 9: 229 – 539 days (25°C) pH 9: 11.8 days (50°C)
Dissociation constant (not stated in Annex IIA or IIIA; additional data	Not applicable, non-ionic material

requirement from TNsG)	
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	maxima at 191 nm and 227 nm
Photostability (DT_{50}) (aqueous, sunlight, state pH) (point VII.7.6.2.2)	No significant absorption > 290 nm. However, in ethanol solutions, irradiated with sunlight or UV lamps, ca. 25 % of the initial IPBC was degraded within 17 days of exposure. A new study demonstrates that IPBC is stable to direct and indirect photolysis in the aquatic environment. This is selected as the key study
Quantum yield of direct photo-transformation in water at Σ > 290 nm (point VII.7.6.2.2)	No significant absorption > 290 nm. Therefore, quantum yield of direct photolysis was not determined.
Flammability	Not highly flammable, not auto flammable
Explosive properties	Not explosive properties.

Classification and proposed labelling (Annex IIA, point IX.)

with regard to physical/chemical data	None
with regard to toxicological data	T, R22, R23, R48/23, R41, R43
with regard to fate and behaviour data	None
with regard to ecotoxicological data	N, R50

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance and the metabolite PBC (principle of method) (Annex IIA, point 4.1)	HPLC-UV GC-FID
Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)	HPLC-UV GC-FID

Analytical methods for residues

Soil (principle of method and LOQ) (Annex IIA, point 4.2)	IPBC/PBC: HPLC-MS/MS, LOQ = 0.01 mg/kg
Air (principle of method and LOQ) (Annex IIA, point 4.2)	Not necessary, IPBC is not volatile and spray applications only involve non-respirable particles.

Water (principle of method and LOQ) (Annex IIA, point 4.2)	IPBC/PBC: Both for surface water, ground water and drinking water. HPLC-MS/MS, LOQ = 0.1 µg/L
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	Relevant residues for monitoring human body fluid and tissues were PBC and IPBC. In blood and muscle IPBC degraded rapidly (to PBC) and it was not possible to determine IPBC residues above 70%. 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. LOQ for PBC and IPBC in urine and blood at 0.05 mg/L. LOQ for PBC and IPBC in meat at 0.1 mg/L.
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not relevant
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not relevant

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals (Annex IIA, VI.6.2)

Rate and extent of oral absorption:	>90% based on urinary excretion (~57-71%) and exhaled air (~18-24%) within 72 hours.

Rate and extent of dermal absorption:	(based on *in vitro* human skin study (Jack & Dunsire, 1995*). 1.6 %* (17% IPBC in a solvent based formulation A) 10 %* (2.4% IPBC in asolvent based formulation B) 30 %* (0.6% IPBC in a solvent based formulation C) 75% default for solutions containing <0.5%-0.6% IPBC. Dermal absorption values used in the applications for product authorisation should be justified, if available by the submission of specific dermal absorption data on the product, or by read-across to existing data if scientifically justified, or by using the default values from the Scientific opinion of EFSA.
Distribution:	Uniformly distributed
Potential for accumulation:	No evidence for bioaccumulation
Rate and extent of excretion:	> 77-99% within 72 hours mainly via urine (57.3 to 70.7%). Excretion in exhaled air was 18.3 to 24.0% and in faeces 4.4%-7.4%.
Toxicologically significant metabolite	Iodine

Acute toxicity (Annex IIA, VI.6.1)

Rat LD_{50} oral	300 – 500 mg/kg bw, **R22**
Rat LD_{50} dermal	> 2000 mg/kg bw/day
Rat LC_{50} inhalation	> 6.89 mg/L technical IPBC (for not respirable dust) 0.67 mg IPBC/L for respirable dust **R23** 0.763 mg IPBC/L for respirable liquid aerosol **R23**
Skin irritation	Non-irritant
Eye irritation	Severe eye-irritant **R41**
Skin sensitization (test method used and result)	Sensitizing (M&K) **R43**

Repeated dose toxicity (Annex IIA, VI. 6.3, 6.4, and 6.5)

Species/ target / critical effect	Rat (oral):

	reduced body weight and body weight gain , increased organ weights (liver and kidney) and increased iron concentration. Histopathological changes in the stomach. Rat (90 day inhalation): histopathological changes in the larynx.
Lowest relevant oral $NOAEL_{short\text{-}term}$	35 mg/kg bw/day (90 day gavage rat)
Lowest relevant oral $NOAEL_{long\text{-}term}$	20 mg/kg bw/day (2 years oral rat)
Lowest relevant dermal NOAEL	90-day dermal study in rats: 200 mg/kg bw/day.
Lowest relevant inhalation NOAEL	90-day inhalation study in rats: 1.16 mg/m^3 **R48/23 (DSD):** Toxic: danger of serious damage to health by prolonged exposure through inhalation. STOT RE 1; H372 (CLP): Causes damage to organs (larynx) through prolonged or repeated exposure (inhalation).

Genotoxicity (Annex IIA, VI.6.6)	The overall weight of evidence indicates that IPBC is not a genotoxic substance.

Carcinogenicity (Annex IIA, VI.6.7)

Species/type of tumour	No evidence for carcinogenic potential in rats and mice.
lowest dose with tumours	Not applicable.

Reproductive toxicity (Annex IIA, VI.6.8)

Species/ Reproduction target / critical effect	Rat: Parents: clinical signs and local effects on the stomach. Developmental: in F1 generation reduced pup viability and cumulative survival index. Reduced pup weight (F1 and F2 females) and increased incidence of pups without milk in stomach and/or bitten or cannibalized at maternal toxic doses. Reproduction: Reduced fertility/mating index at maternal toxic doses.
Lowest relevant reproductive NOAEL	Parental: 10 mg/kg bw/day Developmental: 10 mg/kg bw/day Reproductive: 30 mg/kg bw/day
Species/Developmental target / critical effect	Rabbit: Maternal: not statistically significant reduced

	food consumption in week 1 and one animal that refused to eat due to stomach irritations resulted in body weight loss and subsequent pre-scheduled sacrifice of this animal. Developmental: no treatment related findings.
Lowest relevant developmental NOAEL	Dams: 10 mg/kg bw/day Developmental: 40 mg/kg bw/day

Neurotoxicity (Annex IIIA, VI.1)

Species/ target/critical effect	Rat: *Systemic:* reduced body weight gain/body weight and food consumption at 50 and 120 mg/kg bw/day (m+f). No signs of neurotoxicity have been observed after acute and subchronic oral treatment.
Lowest relevant neurotoxicity NOAEL	120 mg/kg bw/day (90 days oral rat neurotoxicity study).

Other toxicological studies (Annex IIIA, VI/XI)

No data available - not required .

Medical data (Annex IIA, VI.6.9)

No evidence of adverse effects to workers of manufacturing plants or professional painters. Skin sensitisation in workers/patients reported.

Summary (Annex IIA, VI.6.10)	Value	Study	Safety factor
ADI (if residues in food or feed)	0.2 mg/kg bw/day (no correction for oral absorption) relevant for the intended use	2-years rat study	100
$AEL_{long\ term}$	0.2 mg/kg bw/day	2-years rat study	100
$AEL_{medium\text{-}term}$	0.35 mg/kg bw/day	90-day gavage rat study	100
AEL_{acute}	0.35 mg/kg bw/day	90-day gavage rat study	100
ARfD (acute reference dose)	0.35 mg/kg bw/day (no correction for oral absorption)	90-day gavage rat study	100
NOAEC (IPBC)*	1.16 mg/ m^3	Larynx effects in a 90 day rat inhalation study	-

*The listed NOAEC of 1.16 mg/ m^3 for the larynx effects concerns solid IPBC. This is not a NOAEC for products. The NOAEC is proposed to allow for harmonised risk assessment during product authorisation in case inhalation exposure becomes relevant. The relevance of this value has to be considered for the specific products (containing formulants) and the resulting classification of these.

Acceptable exposure scenarios (including method of calculation*)

Industrial use	Acceptable uses identified (with PPE) in the risk characterization of systemic effects (For details of % AEL and MOE (margin of exposure) refer to doc IIB/IIC for the different scenarios.)
Professional use	Acceptable uses identified (with PPE) in the risk characterization of systemic effects. (For details of % AEL and MOE (margin of exposure) refer to doc IIB/IIC for the different scenarios.)
Amateur use	Not relevant for PT13
Secondary exposure	Not relevant for PT13

* please refer to respective tables in doc IIC and doc IIB regarding methods of calculation.

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water (Annex point IIA, VII.7.6; Annex point IIIA, XII.2.1, 2.2)

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pH 4: 267 days (25°C) pH 4: 755 days (12°C)
	pH 7: 248 days (25°C) pH 7: 702 days (12°C)
	pH 9: 229 – 539 days (25°C) pH 9: 648 – 1525 days (12°C) pH 9: 11.8 days (50°C) no major metabolites
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	IPBC is stable to direct and indirect photolysis in the aquatic environment as demonstrated for sterilized buffer and natural pond water at 25°C for up to 3 days
Readily biodegradable (yes/no)	No
Inherent biodegradability	IPBC is primary biodegradable according to Zahn-Wellens test. IPBC degrades rapidly (within 2 hours) to PBC.
Biodegradation in seawater	A study on biodegradation in seawater is not required for PT 13.
Anaerobic water/sediment study: DT_{50} total systems (nonsterile) DT_{90} total systems (nonsterile) DT_{50} total systems (sterile)	**IPBC**: 1.5 hours (for the total system at 22°C) 3.3 hours (for the total system at 12°C) 5.0 hours (for the total system at 22°C) 11 hours (for the total system at 12°C)

DT_{90} total systems (sterile)	13.3 hours at 22°C 30 hours at 12°C 44.3 hours at 22°C 99 hours at 12°C
DT_{50} total systems (nonsterile) DT_{90} total systems (nonsterile)	**PBC**: 11.5 days at 22°C 26 days at 12°C 38.4 days at 22°C 86 days at 12°C
Mineralization (nonsterile)	Mineralization is 10% after 120 days in nonsterile continuous N2 flow samples 21% after 119 days in nonsterile enclosed samples
Mineralization (sterile)	42% after 93 days in nonsterile static samples Mineralization 0%
Non-extractable residues	3.9 – 6.3 % AR after 162/119 days
Distribution in water / sediment systems (active substance)	78% remained in the water phase and less than 10% in the sediment (at day 0)
Distribution in water / sediment systems (metabolites)	Propargyl butyl carbamate (PBC): Up to 88.6 % was available in the water phase (at 8 hours) Up to 13.3% was available in the sediment (at 4 hours) in nonsterile static samples. Up to 20.9 % (at day 1) was available in sterile static samples. 2-propenyl butyl carbamate (2-PBC): Surface water: - up to 34.7 % at day 59 in nonsterile static samples. - up to 35.4 % at day Day 59 in nonsterile enclosed static samples Sediment: - up to 8.0 % at day 59 in nonsterile static samples - up to 8.8 % at day 93 in nonsterile enclosed static samples

Route and rate of degradation in soil (Annex point IIIA, VII.4, XII.1.1, XII.1.4; Annex VI, para. 85)

Mineralization (aerobic)	75.3 % AR after 21 days (nonsterile, 22°C, n = 1) 5.3 % AR after 14 days (nonsterile, 5°C, n =

	1) 2.3 % AR after 28 days (sterile, 22°C, n = 1)
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (22°C, aerobic): 2.1 hours (n = 1) DT_{50lab} (12°C, aerobic): 4.7 hours (calculated according to Arrhenius)
	DT_{90lab} (22°C, aerobic): 7.1 hours (n = 1)
	DT_{50lab} (5°C, aerobic): 8.6 hours (n = 1)
	DT_{50lab} (22°C, anaerobic): 1.5 hours in anaerobic water/sediment systems
Field studies (state location, range or median with number of measurements)	DT_{50f}: not required due to fast degradation of IPBC in soil (DT_{50lab} = 2.1 hours at 22°C)
	DT_{90f}: not required due to fast degradation of IPBC in soil (DT_{90lab} = 7.1 hours)
Anaerobic degradation	See anaerobic water/sediment study
Soil photolysis	Not required because the degradation of IPBC in soil is primarily microbially mediated.
Non-extractable residues	21.4% AR after 14 days which is the maximum value (nonsterile, 22°C, n = 1) 9.6 % AR after 14 days (nonsterile, 5°C, n = 1) 3.0 % AR after 28 days (sterile, 22°C, n = 1)
Relevant metabolites - name and/or code, % of applied active ingredients (range and maximum)	Propargyl butyl carbamate (PBC): 95 % AR after 12 hours DT_{50}: 10 days at 12°C (calculated according to Arrhenius)
Soil accumulation and plateau concentration	Not required due to fast degradation of IPBC in soil

Adsorption/desorption (Annex point IIA, XII.7.7; Annex point IIIA, XII.1.2)

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	Ka: 0.676 – 2.46; Kd: 3.43 – 31.3 (n =5) Ka_{OC}: 61.0 – 309; Kd_{OC}: 457 – 4065 (n =5) Geomean 113.5 (log 2.1) Arithmetic mean: 134.5 Koc (HPLC method): 126 (log Koc = 2.1) no
K_{OC} PBC	198.1 (estimated by PCKOC v1.66)

Fate and behaviour in air (Annex point IIIA, VII.3, VII.5)

Direct photolysis in air	Not studied – no data request
Quantum yield of direct photolysis	No significant absorption > 290 nm. Therefore, quantum yield of direct photolysis was not determined.
Photo-oxidative degradation in air	DT_{50} of 15 hours (for OH radical reaction) derived by the Atkinson method of calculation.
Volatilization	IPBC is only slightly volatile (vapour pressure = 2.36 - 1.4 x 10^{-3} Pa).

Monitoring data, if available (Annex VI, para. 44)

Soil (indicate location and type of study)	No monitoring data for the EU have been reported.
Surface water (indicate location and type of study)	No monitoring data for the EU have been reported.
Ground water (indicate location and type of study)	No monitoring data for the EU have been reported.
Air (indicate location and type of study)	No monitoring data for the EU have been reported.

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group) for IPBC

(Annex IIA, VII. 7.1 - 7.4, Annex IIIA, XII. 2.2 and XII 2.4)

Species	Time-scale	Endpoint	Toxicity
Fish			
Rainbow trout *(Oncorhynchus mykiss)*	96 hours	Mortality	LC_{50}: 0.067 mg/L NOEC: 0.049 mg/L
Fathead minnow (*Pimephales promelas*)	35 days	Larval growth (length and weight)	NOEC: 0.0084 mg/L
Invertebrates			
Daphnia magna	48 hours	Mortality	EC_{50}: 0.160 mg/L EC_0: 0.076 mg/L
Daphnia magna	21 days	Mortality, reproduction and growth effects	NOEC: 0.050 mg/L
Algae			
Scenedesmus subspicatus	72 hours	Growth inhibition	E_bC_{50}: 0.022 mg/L E_rC_{50}: 0.053 mg/L NOEC 0.0046 mg/L
Microorganisms			
Activated sludge	3 hours	Respiration inhibition	EC_{50}: 44 mg/L

Toxicity data for aquatic species (most sensitive species of each group) for PBC
(Annex IIA, VII. 7.1 - 7.3)

Species	Time-scale	Endpoint	Toxicity
Fish			
Rainbow trout *(Oncorhynchus mykiss)*	96 hours	Mortality	LC_{50}: 85.0 mg/L
Invertebrates			
Daphnia magna	48 hours	Mortality	EC_{50}: 60 mg/L EC_0: 17 mg/L
Algae			
Selenastrum capricornutum	96 hours	Growth inhibition	E_bC_{50}: > 41.3 mg/L E_rC_{50}: > 41.3 mg/L NOEC: 21.2 mg/L

Effects on earthworms or other soil non-target organisms
(Annex IIIA, XIII.3.2)

Acute toxicity to earthworm (Annex IIIA, point XIII.3.2)	LC_{50}: > 1000 mg/kg dry soil
Reproductive toxicity to …… (Annex IIIA, point XIII.3.2)	Not required

Effects on soil micro-organisms
(Annex IIA, VII.7.4)

Nitrogen mineralization	EC_{50} value could not be determined
Carbon mineralization	EC_{50}: 312.5 mg/ kg dry soil

Effects on plants
(Annex IIIA, XIII.3.4)

Toxicity to plants (*Avena sativa*)	EC_{50}: 4.92 mg/kg dry soil (based on fresh weigh reduction)

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Effects on terrestrial vertebrates

Acute toxicity to mammals (Annex IIIA, point XIII.3.3)	Not required for Product type 13
Acute toxicity to birds (Annex IIIA, point XIII.1.1)	Not required for Product type 13
Dietary toxicity to birds (Annex IIIA, point XIII.1.2)	Not required for Product type 13
Reproductive toxicity to birds (Annex IIIA, point XIII.1.3)	Not required for Product type 13

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Effects on honeybees (Annex IIIA, point XIII.3.1)

Acute oral toxicity	Not required for Product type 13
Acute contact toxicity	Not required for Product type 13

Effects on other beneficial arthropods (Annex IIIA, point XIII.3.1)

Acute oral toxicity	Not required for Product type 13
Acute contact toxicity	Not required for Product type 13
Acute toxicity to ……..	Not required for Product type 13

Bioconcentration (Annex IIA, point 7.5)

Bioconcentration factor (BCF)	Not relevant for IPBC (see Doc. IIIA, Section 7.4.2 and Section 7.5.5)
Depration time (DT_{50}) (DT_{90})	Not relevant for IPBC (see Doc. IIIA, Section 7.4.2 and Section 7.5.5)
Level of metabolites (%) in organisms accounting for > 10 % of residues	Not relevant for IPBC (see Doc. IIIA, Section 7.4.2 and Section 7.5.5)

Chapter 6: Other End Points

Not applicable, no other end points

Appendix II: List of Intended Uses

	Field of use envisaged	Likely concentration at which IPBC will be used in the:
MG 2 / PT 13 Metalworking fluid preservatives (MWF preservatives)	a) emulsifiable MWF	- biocidal product: 10% - 40% w/w - pre-solution: 0.2% - 4.0% w/w - MWF: 0.005% - 0.1% w/w
	b) water soluble MWF	- biocidal product: 10% - 40% w/w - pre-solution: 0.2% - 4.0% w/w - MWF: 0.005% - 0.1% w/w

Appendix III: List of studies

Data protection is claimed by the applicant in accordance with Article 60 of Regulation (EU) No 528/2012.

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.
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

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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)
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.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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)
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

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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.
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

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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
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

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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.
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

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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
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

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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
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

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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
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

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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
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

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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
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

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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
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.

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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
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)
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

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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)
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)

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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
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

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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
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

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
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)
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)