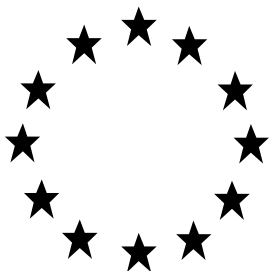
Regulation (EU) n°528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



IPBC

Product-type 6
(Preservatives for products during storage)

September 2013

Denmark

IPBC (PT 6)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 27 September 2013

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Principle of evaluation

This assessment report has been established as a result of the evaluation of IPBC as product-type 6 (In-can preservative), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market[1], with the original view to the possible inclusion of this substance into Annex I or IA to that Directive.

The evaluation has therefore been conducted in the view to determine whether it may be expected, in light of the common principles laid down in Annex VI to Directive 98/8/EC, that there are products in product-type 6 containing IPBC that will fulfil the requirements laid down in Article 5(1) b), c) and d) of that Directive.

1.2. Purpose of the assessment

The aim of the assessment report is to support a decision on the approval of IPBC for product-type 6, and should it be approved, to facilitate the authorisation of individual biocidal products in product-type 6 that contain IPBC. 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.

The conclusions of this report were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Regulation (EU) No 528/2012.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report 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 benefit of another applicant, unless access to these data has been granted.

1.3. Procedure followed

This assessment report has been established as a result of the evaluation of IPBC as product-type 6 (In-can preservative), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market.

1 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing biocidal products on the market. OJ L 123, 24.4.98, p.1

IPBC (CAS no. 55406-53-6) was notified as an existing active substance, by members of 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 PT6. ISP Switzerland AG changed the legal entity to ISP Switzerland GmbH.

Commission Regulation (EC) No 1451/2007 of 4 December 2007[2] lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.

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 IPBC as an active substance in Product Type 6 was 31 July 2007, in accordance with Article 9 (c) 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 27 June 2011, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 29 June 2011. The competent authority report included a recommendation for the inclusion of IPBC in Annex I to the Directive for product-type PT6.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 1 July 2011. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

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 Commission. Revisions agreed upon were presented at technical and competent authority meetings and the competent authority report was amended accordingly.

In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 27 September 2013.

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2 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

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physical-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. 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.

The methods 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.

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. The use of IPBC as an in-can preservative result to a low concentration of IPBC in the end-product (0.01-1%). Therefore, the amount of IPBC

transferred to food or feeding stuff from material treated with the end-product is considered to be negligible.

2.1.2. Intended Uses and Efficacy

The assessment of the biocidal activity of the active substance IPBC demonstrates that it has a sufficient level of efficacy against fungi and yeast and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that IPBC-based in-can preservative products may be expected to be efficacious. The biocidal products produced by the TF members for in-can preservation have typical concentrations in the range of 10 to 30% IPBC. In end-use products, IPBC is contained at concentrations ranging from 0.01 to 1%.

The intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

The risk of resistance formation against carbamate fungicides is regarded to be low to medium by FRAC (Fungicide Resistance Action Committee). This applies to the use of carbamate fungicides in agriculture, where yearly applications to the same fields are possible. Based on the unspecific mode of action of IPBC, the risk of resistance formation during in-can preservation is regarded to be low.

2.1.3. Classification and Labelling -proposed classification and labelling for the active substance IPBC

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

Classification		
Class of danger	T N	Toxic Dangerous for the environment
R phrases	R22 R23 R37 R41 R43 R50	Harmful if swallowed. Toxic by inhalation Irritating to respiratory system Risk of serious damage to the eye May cause sensitization by skin contact Very toxic to aquatic organisms.
S phrases	S1 S23 S24/25	Keep locked up. Do not breathe vapour/spray Avoid contact with skin and eyes

	S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
	S36/37/39	Wear suitable protective clothing, gloves and eye/face protection.
	S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
	S61	Avoid release to the environment. Refer to special instructions/Safety data sheets.

Proposed classification based on Regulation EC 1272/2008:

Signal Word	Danger
Pictograms	GHS05, GHS06, GHS09
Hazard class and category code(s)	Acute Tox 3 Eye Dam. 1 Acute Tox 4 Skin Sens. 1 STOT SE3 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 H335: May cause respiratory irritation H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long-lasting effects*
Environmental M-factor	10 (acute), 1* (chronic)

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

* According to Commission Regulation (EU) No 286/2011 (2nd ATP)

The Committee for Risk Assessment (RAC) has in addition recently proposed to classify IPBC with STOT RE 1 based on effects seen on larynx after prolonged exposure by inhalation. This proposal has not yet been adopted by the REACH Committee.

The final classification must when adopted by the REACH Committee be considered during the authorization of biocidal products.

2.1.4. Classification and Labelling -proposed for the representative biocidal products

Classification on the basis of toxicological and environmental effects of the biocidal products shall, in the absence of experimental data, be deduced from the respective properties of the active substance(s) and the inactive ingredients on the basis of the conventional (calculation) method referred to in Article 6 and Annex II (tox.) and Article 7 and Annex III, Parts A and B (environment) of Directive 1999/45/EC. Classification on the basis of toxicological properties from experimental data is only allowed if test results on animals already exist or it can be scientifically demonstrated that the toxicological properties of the preparation cannot correctly be determined by the conventional method.

The formulation consists of two ingredients, namely 30% of the active substance IBPC (3-Iodo-2-propynyl butylcarbamate) and the solvent Dipropylene glycol. Only IPBC has properties, which lead to a classification according to the relevant guidelines.

The classification of the formulation as "harmful if swallowed", "toxic by inhalation", "irritating to respiratory system, "risk of serious damage to eyes" as well as "may cause sensitization by skin contact" was made on the basis of the conventional method of Directive 1999/45/EC and is based on the toxicological properties of IPBC.

The classification as "dangerous for the environment" according to Directive 2001/59/EC is based on the ecotoxicological properties of IPBC.

Classification		
Class of danger	T N	Toxic Dangerous for the environment
R phrases	R22 R23 R37 R41 R43 R50	Harmful if swallowed. Toxic by inhalation Irritating to respiratory system Risk of serious damage to the eye May cause sensitization by skin contact Very toxic to aquatic organisms.
S phrases	S1 S23 S24/25 S26	Keep locked up. Do not breathe vapour/spray Avoid contact with skin and eyes In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

	S36/37/39	Wear suitable protective clothing, gloves and eye/face protection.
	S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
	S61	Avoid release to the environment. Refer to special instructions/Safety data sheets.

The following classification is proposed in accordance with the latest classification and labelling guidance (Regulation (EC) No. 1272/2008):

Labelling elements based on the classification	
GHS pictogram	GHS05, GHS06, GHS09
Signal word	Danger
Hazard class and category code(s)	Acute Tox 3 Eye Dam. 1 Acute Tox 4 Skin Sens. 1 STOT SE3 Aquatic Acute 1 Aquatic Chronic 1*
Hazard statements	H331: Toxic if inhaled H302: Harmful if swallowed H317: May cause an allergic skin reaction H318: Causes serious eye damage H335: May cause respiratory irritation H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long-lasting effects*
Environmental M-factor	10, 1*

* According to Commission Regulation (EU) No 286/2011 (2nd ATP)

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

The final classification must when adopted by the REACH Committee be considered during the authorization of biocidal products.

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. IPBC is 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 dermal absorption values (including skin residues) of 30, 10, and 1.6% for formulations containing 0.6, 2.3, and 17.1% IPBC, respectively. Solvents were xxxxxxx respectively.

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 gastrointestinal 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

2.2.1.3. Risk characterisation for local effects

It was decided at TMIV2011 that a quantitative RA should only be carried out if suitable data is available for the product (e.g product were a dilution of the active substance). In the situation with IPBC the model product, contains formulants and thus is not just a dilution of the active substance. In line with the decision taken at TMIV2011, a qualitative local risk assessment describing the effects and including the C&L of the products has been performed.

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 R37: **Irritating to respiratory system.**

Only products used for in-can preservation by professionals in automated processes will be classified with R37 (10-40% a.i) and thus PPE can be prescribed. For all other uses both for professionals and amateurs the application/handling of the end products, which contains 0.01-1% IPBC, will not lead to classification of the end products with R37.

In conclusion, a local exposure assessment is not required even if a worst case approach based on the R37/STOT SE 3 classification is taken. The concentration of IPBC in all liquid formulations applied in PT6 is below 20% which is the threshold for a classification of a mixture as a respiratory irritant according to the provisions of the DPD and the CLP. Consequently, as no respiratory 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. 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.

The representative product containing IPBC is also classified as a severe eye irritant and skin sensitiser. However, at the end use concentration of the product the risk with regard to these hazardous properties is considered to be acceptable.

Despite the moderate sensitizing property of IPBC, based on the risk assessment no specific concern is identified due to use of treated articles intentionally incorporating IPBC. Therefore, there is no need to set restrictions or specific conditions for use of IPBC in similar type of applications as evaluated in this CAR.

2.2.1.4. Systemic exposure assessment and risk characterisation

Industrial application

Exposure during industrial in-can preservation of washing, cleaning fluids, detergents, paints and coatings, fluids used in paper, textile and leather production, glues and adhesives is displayed in Table 1-1 in doc IIC. Assuming concentrations in the range of 10 to 40 %, exposure during in-can preservation is between 0.0010 to 0.0024 mg/kg bw/day when wearing PPE. These exposure figures do not exceed the long term AEL of 0.2 mg/kg bw/day (equivalent to 0.51 – 1.2% of the $AEL_{long\text{-}term}$).. The MOE is above 8357. Thus, the risk for the industrial workers during in-can preservation is considered to be acceptable.

The industrial application of in-can preserved paints and coatings results in an exposure of 0.000053 to 0.00053 mg/kg bw/day when spraying at concentrations of 0.01 and 0.1 %, respectively and wearing PPE (see Table 1-1 in doc IIC). These exposures are below 1 % of the AEL for long-term exposures of 0.2 mg/kg bw/day. The MOE is above 10000. Thus, the risk for the industrial workers during application of in-can preserved paints and coatings is considered to be acceptable.

The use of in-can preserved fluids for paper, textile and leather production (IPBC concentration: 0.1%) and glues and adhesives (IPBC concentration: 1%) result in exposures of 0.037 and 0.025 mg/kg bw/day (concentration 0.1-1 %) when wearing PPE. This equals to 18.7 and 12.54 % of $AEL_{long\text{-}term}$ of 0.2 mg /kg bw/day. The MOE is above 500. Thus, the risk for the industrial workers during application of in-can preserved fluids for paper, textile and leather production and glues and adhesives is demonstrated to be acceptable.

Professional application

When IPBC preserved washing and cleaning fluids or detergents are applied by professionals (including handling of the wet treated laundry for instance) the exposure is 0.000296 mg/kg bw/day (equal to 0.15 % of $AEL_{long\text{-}term}$ of 0.2 mg/kg bw/day) when wearing PPE. When applying the in-can preserved paints, coatings, glues and adhesives by manual spraying, brushing, or wallpapering, the exposures are in the range of 0.00089 to 0.03 mg/kg bw/day when wearing PPE. These exposures are well below the $AEL_{long\text{-}term}$ of 0.2 mg/kg bw/day (0.45 to 15. % of $AEL_{long\text{-}term}$). The MOE is above 700 in all scenarios.

Consequently, the risk for professionals during the intended biocidal uses of IPBC in PT6 has been demonstrated to be acceptable.

Amateur application

The results of the amateur/consumer exposure estimations for IPBC when using in-can preserved cleaning and washing fluids, detergents (for hand dish washing), paints and coatings (for manual spraying and brushing) and glues and adhesives (for wallpapering) are shown in Table 1-3 in doc IIC. The estimated exposures are in the range of 0.002 to 0.187 mg/kg bw/day when no PPE is worn. In all scenarios concerning amateur/consumer exposure, the AEL for longand short/medium- term exposure is not exceeded (1% of long-term AEL and max 53.43% of the short-term AEL, respectively). The MOE is above ~ 190 in all non-professionals use scenarios. These applications are therefore considered to be of acceptable risk.

Risk Characterisation for Secondary exposure

A secondary exposure and risk assessment has been performed for the following scenarios:

- Consumption of food after contact to cleaned or painted surface
- Exposure *via* residues from cleaned dishes
- Contact of child and infant to cleaned or painted surface or glues
- Contact of child and infant to residual IPBC in textiles after laundry
- Inhalation of volatilized residues indoors

For all secondary exposure assessments, worst case assumptions were made, i.e. assuming the maximum concentrations.

The oral exposure *via* residues from food in contact with cleaned or painted surfaces or from cleaned dishes was estimated to be in the range of $9.9*10^{-6}$ mg/kg bw/d $8*10^{-4}$ mg/kg bw/day for adults, children and infants, respectively, which is equivalent to 0.005% to 0.4% of the $AEL_{long\text{-}term}$.

The combined oral and dermal exposure of children and infants during playing on treated or painted surface or when touching glues containing IPBC has been estimated to amount to $3.98*10^{-3}$ and 0.0139 mg/kg bw/ day, respectively. Which is equivalent to 1.99% and 6.95% of the $AEL_{long\text{-}term}$ of 0.2 mg/kg bw/day.

The dermal exposure of children and infants via residues of IBPC in textiles after laundry results in an exposure of $1.3*10^{-6}$ to $1.86*10^{-6}$ mg/kg bw/ day, respectively which is equivalent to less than 0.1% of the $AEL_{long-term}$.

The inhalation exposure of adults, children and infants to residues volatilizing from residues was estimated to be in the range of $1.09*10^{-3}$ to $1.57*10^{-3}$ mg/kg bw/day, equivalent to < 1% of the $AEL_{long-term}$.

The risk during secondary exposure to IPBC is considered to be acceptable because the $AEL_{long-term}$ is not exceeded. The MOE is calculated to be above 1400 for all secondary exposure scenarios.

Combined exposure

Adults are the only subpopulation who may reasonably experience both primary and secondary exposure to IPBC. Since the secondary exposure adds only negligible doses to the primary exposure, no additional concern arises from the combination of all pathways. Even in the worst case scenario of a professional who is involved in industrial in-can preservation or industrial use of in-can preserved end-products, manual spraying and brushing in his or her leisure time, the MOE of the primary exposure scenario remains virtually unchanged and sufficiently high.

Overall conclusion

The use of IPBC in industrial in-can preservation and the further use of the in-can preserved end-products can be considered safe for industrial, professional and non-professional users. Furthermore, the secondary exposure is negligible or very low and does not pose a unacceptable risk for human health. Thus the overall outcome of the systemic risk assessment for humans, that has covered normal/representative use of the biocidal 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 and in-can preserved end-products therewith is considered safe for all subpopulations.

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. 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 hour at 12°C. In degradation of IPBC, the primary degradate 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 degradates (less than 10%), CO_2 and possibly CH_4. The metabolite 2-PBC is only formed at a percentage > 10% in the water phase under anaerobic conditions. QSAR estimation indicates a toxicity of this metabolite 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 PT6; 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 are 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 P_{ow} value of 2.8.

2.2.2.2. Effect 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. Tests are available for test 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 PNEC values from the first Draft CAR of iodine from SE is used.

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 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 ED assessment

Assessment of PBT criteria

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 22º C (DT_{50} of 4.7 hours at 12 º C). In a water sediment study a DT_{50} of 1.4 hour at 22º C (DT_{50} of 3.1 hours at 12 º C) was found for the water phase and a DT_{50} of 2.2 hour at 22º C (DT_{50} of 4.9 hours at 12 º C) 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 º C), in sediment the DT50 value is 14.3 days at 22 ºC (DT_{50} of 31.4 days at 12 º C) while the degradation half-live in soil of PBC is 4.3 days at 22 ºC (DT_{50} of 9.5 days at 12 º C). 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 P_{ow} 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 Kow 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.

Assessment of Endocrine Disruption (ED)

IPBC nor PBC are not included in the EU list of potential endocrine disruptors (COM DG ENV, 2000).

2.2.2.4. Exposure assessment

For the exposure assessment, two approaches have been used, i.e. a consumption and a tonnage based approach. For the consumption based approach penetration factors of 1 and 0.5 have been applied to uses where there is a direct disperse emission to the STP. Using a penetration factor of 0.5 is a refinement that is performed as several substances are used for in-can preservation.

For the consumption based approach, emissions are calculated based on several different emission scenario documents (ESDs) as recommended in the ESD for PT6. The different uses of IPBC result in emissions directly into soil, the facility drain or the air. For the consumption based approach emissions from the formulation of the end-products are considered negligible as the process of in-can preservation is highly automated. The exposure assessment therefore covers the application phase of the end-products treated with preservative and their service life, covering all the applications listed:

PT6.1 In-can preservation of washing and cleaning fluids and detergents

PT6.2 In-can preservation of paints and coatings

PT6.3.2 In-can preservation of fluids used in textile production

PT6.6 Glues and adhesives

For the tonnage based approach exposure calculations cover both the formulation and the use of the end-products. For the formulation phase local emissions were calculated using the default values provided in A&B tables of the TGD Part II (2003) for the respective industries. For the use phase it is assumed that 100% of the used IPBC is emitted to the facility drain, except for paints where default values from the ESD for PT7 have been used as refinement (0% release for professional use and 3% release for non-professional use). For the industrial use under PT6.2 it is assumed that this part is covered by the professional use. For glues and adhesives which are used indoors, it is assumed that it result in emissions of IPBC to air but not to the facility drain. For the tonnage based approach only the emissions to the STP are considered as the other emissions are covered by the consumption based approach as these emissions are higher than those for the tonnage based approach.

As IPBC quickly degrades to PBC, iodide and iodate within the environmental compartments, PEC calculations of IPBC, 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. For the evaluation of IPBC in PT8, inlet concentrations of IPBC were used to evaluate the risk for the STP. For PT8 PEC/PNEC (STP) ratios were low and it made no difference if the risk characterisation was based on IPBC or PBC; whereas for IPBC in PT6, PEC/PNEC (STP) ratios are closer to 1 so it makes a difference which ones are evaluated. It is therefore chosen to use the approach with STP effluent concentrations according to the TGD for this evaluation.

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. For the exposure assessment of iodide and iodate, calculations for the direct emissions to STP are based on the tonnage based approach. The reason for this is that the final risk assessment of IPBC/PBC is based on the tonnage approach and acceptable risk is found; furthermore the evaluation of iodine/iodate was added late in the process (in the final draft CAR) and for saving the amount of work only the last tier was chosen. However, the consumption based approach is applied for direct emissions to soil as this is not covered in the tonnage based approach.

2.2.2.5. Risk characterisation

IPBC released directly to the facility drain

Several of the usages of IPBC as in-can preservative result in direct emissions to a STP, these emissions can end up in the same STP and in the same environmental compartments following the STP. A cumulative risk assessment is therefore performed for these emissions based on a tiered approach. For Tier 1 all emissions to STP are evaluated together. However, it is not likely that all the industries are in the same catchment area to a STP; this approach is therefore only used as a worst case. For Tier 2 the total domestic emission is considered together while emissions from industries are evaluated separately.

Considering PBC (consumption and tonnage based approach)

In the risk characterisation it is found that the consumption based approach results in PEC/PNEC ratios much higher than those for the tonnage based approach, both when considering market penetration factors of 1 and 0.5.

For the consumption based approach the requirements for acceptable risk according to the TGD on Risk Assessment are met for all the single uses of IPBC. However, when considering the cumulative risk (Tier 1: all domestic and industrial emissions together) risk is found for the sewage treatment plant and the surface water for marked penetration factors of both 1 and 0.5. When considering the total domestic load (Tier 2) for the consumption based approach no unacceptable risk is identified for any environmental compartments for marked penetration factors of both 1 and 0.5. Also when the total domestic load is combined with any single industrial emission, no unacceptable risk is found for a marked penetration factor of 0.5. For a

marked penetration factor of 1 unacceptable risk is found for the STP and the surface water when the total domestic load is combined with industrial emissions from either washing and cleaning fluids or textile production.

For the tonnage based approach for applications considered in this dossier the requirements for acceptable risk according to the TGD on Risk Assessment in the STP, the surface water compartment as well as the soil compartment are met. Also when considering the cumulative emission from all the formulations and usages no unacceptable risk is identified.

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.

Considering iodide and iodate (only tonnage based approach)

In the risk characterisation performed for the degradation products iodide and iodate unacceptable risk is identified for iodide in surface water and soil. For soil, predicted concentrations are well within the background level which is found acceptable. For surface water the predicted concentrations of both iodide and iodate are within the background level but close to the highest level. Under oxic conditions iodine is mainly present as iodate which would mean risk ratios below 1. 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 result in lower concentrations in surface water and higher concentrations in sediment and suspended matter. Further it should be mentioned, that the calculations are considering the cumulative emission from all the formulations and usages.

For sediment and groundwater predicted concentrations of iodide and iodate are well within the background levels, which is found acceptable.

IPBC released directly to soil

IPBC is released directly to soil when used in paints applied to houses in the countryside. IPBC, PBC, iodide and iodate are evaluated as IPBC quickly degrades in soil. For the release during treatment acceptable risk according to the TGD is identified shortly after application for IPBC and for PBC considering a distance and depth of 10 cm from the treated surface. Initial risk is therefore accepted as the risk is reduced by a PEC/PNEC value far below 1 on time1 for IPBC and PBC, respectively. For release during service life the risk is unacceptable for IPBC and PBC within the initial assessment period, while the risk is acceptable within the longer assessment period when the 10 cm distance and depth is considered. When considering a 50 cm distance and depth, the PEC/PNEC values are below 1, showing an acceptable risk for both the initial and longer assessment period.

The PEC/PNEC ratios for iodide are slightly above 1 both for the application phase and the service life when considering a distance and depth of 50 cm and below 1 for the distant soil for the spraying treatment. For iodate the PEC/PNEC ratios are above 1 when considering a distance and depth of the soil of 10 cm; however, the PEC values of iodide and iodate are all well within the background level (0.5-20 mg/kg dwt). The risk is therefore found acceptable both for iodate as well as for iodide.

In line with the conclusion from the first Draft CAR of iodine from SE stating that: considering the high background iodine concentrations in the environmental compartments concerned and that iodine is an essential element to both animals and plants in rather high concentrations (higher than what corresponds to a trace element), the actual risks arising from the use should be considered to be acceptable as predicted concentrations are below the background level.

Atmosphere and groundwater

Direct exposure to air from the described use of IPBC in PT6 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 1.21×10^{-6} mg/m^3. 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 models PELMO and 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. By using the FOCUS model PEARL it could be shown that the estimated concentrations of Iodide and Iodate are within the background level of 1-70µg/L in eight of the nine considered scenarios. In one scenario the estimated concentration is only slightly above the background level of 70 µg/L. The assessment is however worst case since it was assumed that all the industries (formulation of end-products as well as the industrial use of end-products are in the same catchment area to a STP. The risk is therefore found acceptable both for iodate as well as for iodide.

2.2.3. List of endpoints

In order to facilitate the work of Member States in granting or reviewing authorisations, the most important endpoints, as identified during the evaluation process, are listed in Appendix I.

In the list of endpoints analytical methods for residues in tissue and body fluids have been added compared to the one displayed for IPBC in PT8.

3. PROPOSED DECISION

3.1. Background to the proposed decision

IPBC has a proposed classification as Acute Tox 3, Eye Dam. 1, Acute Tox 4, Skin Sens. 1, STOT SE3, Aquatic Acute 1, Acute Chronic 1 with H331, H318, H302, H317, H335, H400 and H410 (T, N, R22-23-37-41-43-50).

The assessment has been performed based on the documentation for the active substance and the representative biocidal solvent based model formulation containing 30% IPBC. The biocidal product is intended to control fungi and yeast and is for industrial in-can preservation process. The concentration of IPBC in the product to be preserved is in the range of 0.01% to 1.0%. The end-products cover washing and cleaning fluids and other detergents, paint and coatings, fluids used in textile production and glues and adhesives for indoor use.

The assessment of the biocidal activity of the active substance IPBC demonstrates that is has a sufficient level of efficacy against fungi and yeast and efficacy results show that IPBC based in-can preservative products may be expected to be efficacious. However, further efficacy data may be required on specific products to support product authorisation at Member State level.

The risk characterisation for human health indicates that there is no unacceptable risk anticipated for industrial workers during in-can preservation and during application of in-can preserved products.

In the risk characterisation for the environment, results from the consumption based approach show no unacceptable risk for all the single uses of IPBC. However, when considering the cumulative risk (Tier 1: all domestic and industrial emissions together) risk is found for the sewage treatment plant and the surface water for marked penetration factors of both 1 and 0.5. When considering the total domestic load (Tier 2) for the consumption based approach no unacceptable risk is identified for any environmental compartments for marked penetration factors of both 1 and 0.5. Also when the total domestic load is combined with any single industrial emission, no unacceptable risk is found for a marked penetration factor of 0.5. For a marked penetration factor of 1 unacceptable risk is found for the STP and the surface water when the total domestic load is combined with industrial emissions from either washing and cleaning fluids or textile production. For the tonnage based approach for applications considered in this dossier the requirements for acceptable risk according to the TGD on Risk Assessment in the STP, the surface water compartment as well as the soil compartment are met. Also when considering the cumulative emission from all the formulations and usages no unacceptable risk is identified. In the risk characterisation performed for the degradation products iodide and iodate unacceptable risk is identified for iodide in surface water and soil. For soil, predicted concentrations are well within the background level which is found acceptable. Further, there was no risk identified for contamination of groundwater at levels of 0.1 µg/L or above for IPBC and the degradation product PBC. For the degradation products iodide and iodate expected levels are within the background level of 1-70 µg/L in eight of the nine considered scenarios. In one scenario the estimated concentration is only slightly above the background level of 70 µg/L. IPBC and PBC are also not characterised as PBT substances since only the criterion for toxic (T) is fulfilled for IPBC.

Assessed from the documentation for the active substance, IPBC, and the representative artificial “dummy” product containing IPBC, the proposed manner and areas of use of products

intended to control fungi and yeast may be sufficiently effective for these uses and without unacceptable risk either to human health or to the environment.

This overall conclusion relies on the fact that users of the biocidal product will be applying the basic principles of good practice and respect the conditions for use recommended on the label of the product.

3.2. Proposed decision

The overall conclusion from the evaluation of IPBC for use in Product Type 6 (Preservatives for products during storage), is that it may be possible to issue authorisations of products containing IPBC in accordance with the conditions laid down in Article 5(1) b), c) and d) of Dir. 98/8/EC.

It is therefore proposed to approve IPBC as an active substance for use in product-type 6 (preservatives for products during storage), subject to the following specific conditions:

The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

Authorisations are subject to the following condition:

For industrial or professional users, safe operational procedures and appropriate organizational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment. Where a treated article has been treated with or intentionally incorporates IPBC, and where necessary due to the possibility of skin contact as well as the release of IPBC under normal conditions of use, the person responsible for placing the treated article on the market shall ensure that the label provides information on the risk of skin sensitisation, as well as the information referred to in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.

3.3. Elements to be taken into account when authorising products

Products containing IPBC have been evaluated for the use to control fungi as an in-can preservative.

The following manner and area of use of products containing IPBC have been evaluated with the following specified maximum concentrations of IPBC:

PT 6 In-can preservative	Field of use envisaged for in-can preservation in:*	Concentration at which IPBC have been evaluated: **
	6.1 Washing and cleaning fluids and detergents Industrial in-can preservation process Industrial, professional and non-professional use of end-products	biocidal product: 15% - 30% end-product: 0.1%

PT 6 In-can preservative	Field of use envisaged for in-can preservation in:*	Concentration at which IPBC have been evaluated: **
	6.2 Paints and coatings Industrial in-can preservation process Industrial, professional and non-professional use of end-products	biocidal product: 30% end-product: 0.01% - 0.1%
	6.3.2 Fluids used in textile production Industrial in-can preservation process Industrial and professional use of end-products	biocidal product: 30% end-product: 0.1%
	6.6 Glues and adhesives (indoor) Industrial in-can preservation process Industrial, professional and non-professional use of end-products	biocidal product: 10% - 30% end-product: 1%

* The source for categorisation is Van der Poel and Bakker (2001) and modified after Doc. 6.4 from 41st CA meeting.

** The concentration is given in % (w/w). A product containing 30% IPBC was chosen as the representative model formulation. However, in the human health exposure and risk assessments biocidal products with an IPBC concentration in the range of 10-40% have been evaluated.

The following uses within PT6 have not been evaluated: In-can preservation of fluids used in paper production, fluids used in leather production, metal working fluids, fuels and glues and adhesives for outdoor use.

If products containing the active substance is recommended for preserving paper that comes into contact with food a dietary assessment may be necessary. This should be taken into account at product authorisation.

In the product authorisation phase, simulated use studies are required on the efficacy of the test substance over longer periods of time and on the effects of interfering substances in the products to be preserved

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 default values.The final classification must when adopted by the REACH Committee be considered during the authorization of biocidal products.

3.4. Requirement for further information

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the approval of IPBC in accordance with Article 9 of Regulation No 528/2012.

3.5. Updating this Assessment Report

This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information submitted in relation with Regulation (EU) No 528/2012. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the approval of IPBC.

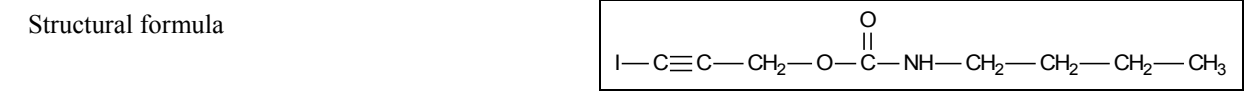
Appendix I: List of endpoints

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 × 10^{-3} Pa (at 25 °C)
Henry's law constant (Pa m^3 mol^{-1})	3.38-6.45 × 10^{-3} Pa × m^3 × 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 requirement from TNsG)	Not applicable, non-ionic material
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, R37, 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 necessary. The use of IPBC as an in-can preservative result to a low concentration of IPBC in the end-product (0.1%). Therefore, the amount of IPBC transferred to food or feeding stuff from material treated with the end-product is considered to be negligible (see Doc. IIB chapter 8.2.2.1).
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not necessary. See above.

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:	1.6 % (17% IPBC in xxxxxxxx) 10 % (2.4% IPBC in xxxxxxxx) 30 % (0.6% IPBC in xxxxxxx) 100% default for solutions containing <0.5%-0.6% IPBC 1.6% for solid formulations and dried solutions (based on *in vitro* human skin study (Jack & Dunsire, 1995).
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 were 18.3 to 24.0% and in faces 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.
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 R37: Irritating to respiratory system.

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 rats study	100
$AEL_{long\ term}$	0.2 mg/kg bw/day	2-years rats 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

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 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 for the different scenarios.)
Amateur use	Acceptable uses identified in the risk characterization of systemic local effects. (For details of %AEL and MOE (margin of exposure) refer to doc IIB for the different scenarios.)
Secondary exposure	Secondary exposure levels are low and acceptable. (For details of %ADI/AEL and MOE (margin of exposure) refer to doc IIB for the different scenarios.)

* please refer to Table 1-2 and Table 1-3 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 6.
Anaerobic water/sediment study:	**IPBC**:
DT_{50} total systems (nonsterile)	1.5 hours (for the total system at 22°C) 3.3 hours (for the total system at 12°C)
DT_{90} total systems (nonsterile)	5.0 hours (for the total system at 22°C) 11 hours (for the total system at 12°C)
DT_{50} total systems (sterile)	13.3 hours at 22°C 29 hours at 12°C
DT_{90} total systems (sterile)	44.3 hours at 22°C 96 hours at 12°C
DT_{50} total systems (nonsterile)	**PBC**: 11.5 days at 22°C
DT_{90} total systems (nonsterile)	25 days at 12°C 38.4 days at 22°C 83 days at 12°C
Mineralization (nonsterile)	Mineralization is 10% after 120 days in nonsterile

Mineralization (sterile)	continuous N2 flow samples 21% after 119 days in nonsterile enclosed samples 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: 0.676 – 2.46; Kd: 3.43 – 31.3 (n =5)
Ka_{oc} , Kd_{oc}	Ka_{OC}: 61.0 – 309; Kd_{OC}: 457 – 4065 (n =5) Geomean 113.5 (log 2.1) Arithmetic mean: 134.5
pH dependence (yes / no) (if yes type of dependence)	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)

Effects on terrestrial vertebrates

Acute toxicity to mammals (Annex IIIA, point XIII.3.3)	Not required for Product type 6
Acute toxicity to birds (Annex IIIA, point XIII.1.1)	Not required for Product type 6
Dietary toxicity to birds (Annex IIIA, point XIII.1.2)	Not required for Product type 6
Reproductive toxicity to birds (Annex IIIA, point XIII.1.3)	Not required for Product type 6

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

Acute oral toxicity	Not required for Product type 6
Acute contact toxicity	Not required for Product type 6

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

Acute oral toxicity	Not required for Product type 6
Acute contact toxicity	Not required for Product type 6
Acute toxicity to ……..	Not required for Product type 6

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

Summary of intended uses for IPBC-based in-can preservation products (PT6)

Object and/or situation	Member State or Country	Product name	Organisms controlled	Formulation		Application			Applied amount per treatment			Remarks:
(a)			(c)	Type (d-f)	Conc. of as (i)	method kind (f-h)	number min max (k)	interval between applications (min)	g as/L min max	water L/m^2 min max	g as/m^2 min max	(m)
In-can preservation	EU	n.a.	Fungi including yeasts	n.a.	10%-30%	The in-can preservation product containing IPBC is added to the products to be preserved in an automated process. The end-products cover washing and cleaning fluids and other detergents, paints and coatings, fluids used in textile production and glues and adhesives for indoor use. One application / can			The concentration of IPBC in the product to be preserved is in the range of 0.01% to 1.0%			In-can preservation process: Professionals End products can be used by professionals and amateurs.

(a) *e.g.* biting and suckling insects, fungi, molds;
(b) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(c) GCPF Codes - GIFAP Technical Monograph No 2, 1989 ISBN 3-8263-3152-4);
(d) All abbreviations used must be explained
(e) g/kg or g/l;
(f) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench;
(g) Kind, *e.g.* overall, broadcast, aerial spraying, row, bait, crack and crevice equipment used must be indicated;
(h) Indicate the minimum and maximum number of application possible under practical conditions of use;
(i) Remarks may include: Extent of use/economic importance/restrictions

Appendix III: List of studies

The Doc IIIA Reference list sorted by Section No:

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)

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

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

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

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

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

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

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

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

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A6.7/02 Submitted with the PT8 BPD dossier	XXXX	1988	3-iodo-2-propynyl butyl carbamate (IPBC) chronic dietary toxicity study in rats Source: XXXX Report No.: 5261 XXXX 435580 TC1417 GLP; (unpublished) Doc. No.: 537-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.7/03 Submitted with the PT8 BPD dossier	XXXX	1995	Review and interpretation of selected thyroid and forestomach lesions in the carcinogenicity study of 3-iodo-2-propynyl butyl carbamate (IPBC) in sprague-dawley rats Source: XXXX Report No.: TC-0476 Not GLP; (unpublished) Doc. No.: 581-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.7/04 Submitted with the PT8 BPD dossier	XXXX	1989	IPBC 78 week dietary carcinogenicity study in mice Volume 1 to 3 (803 pages) Source: XXXX Report No.: TC-0409 7304 436165 GLP; (unpublished) Doc. No.: 555-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
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

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

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

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A6.8.2/07 Submitted with the PT8 BPD dossier	Shaw, D.	2004	To whom it may concern - IPBC purity Source: Troy Corporation, USA Report No.: Not applicable Not GLP; (unpublished) Doc. No.: 593-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.9/01 Submitted with the PT8 BPD dossier	XXXX	2002	Acute oral dose range-finding study with 3-iodopropynylbutyl carbamate (IPBC) administered by Gavage in CD rats Source: XXXX Report No.: 7071-100 TC-1414 GLP; (unpublished) Doc. No.: 541-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation ARCH Chemicals
A6.9/02 Submitted with the PT8 BPD dossier	XXXX	2001	Acute oral neurotoxicity study with 3-iodopropynylbutyl carbamate (IPBC) administered by gavage in CD rats - Volume 1 of 3 Source: XXXX Report No.: 7071-101 TC-1059 GLP; (unpublished) Doc. No.: 541-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals TROY Corporation
A6.9/03 Submitted with the PT8 BPD dossier	XXXX	2001	Acute oral neurotoxicity study with 3-iodopropynylbutyl carbamate (IPBC) administered by gavage in CD rats - Volume 2 of 3 Source: XXXX Report No.: 7071-101 TC-1059 GLP; (unpublished) Doc. No.: 541-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals TROY Corporation
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

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

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

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

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

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

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

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

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

The Doc IIIB reference list sorted by Section No:

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
B6.1.1 Submitted with the PT6 BPD dossier	Hernandez, O.	2001	Dipropylene glycol (mixture of isomers and Dominant Isomer CAS N°: 25265-71-8 & 110-98-5) Source: UNEP Publications, 2002, 1-84 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-021	No	N.R.
B7.1.1/01 Submitted with the PT6 BPD dossier	Klamer, M.	2007	Field Leaching Study of IPBC from Painted Surfaces Exposed to Outdoor Conditions (Natural Rain) - Preliminary Results Source: Danish Technological Institute, Toastrup, Denmark Report No.: 1006657-17 180401 Not GLP; (unpublished) Doc. No.: 732-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, DOW, ISP. LANXESS, TROY)
B7.1.1/01 Submitted with the PT6 BPD dossier	Klamer, M.	2008	Field Leaching Study of IPBC from Painted Surfaces Exposed to Outdoor Conditions (Natural Rain) Source: Danish Technological Institute, Toastrup, Denmark Report No.: 1006657-17 Not GLP; (unpublished) Doc. No.: 732-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, DOW, ISP. LANXESS, TROY)
B7.1.1/01 Submitted with the PT6 BPD dossier	Klamer, M.	2008	1st Amendment to the report: Field Leaching Study of IPBC from Painted Surfaces Exposed to Outdoor Conditions (Natural Rain) - Preliminary Results Source: Danish Technological Institute, Toastrup, Denmark Report No.: 1006657-17 Not GLP; (unpublished) Doc. No.: 732-007	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, DOW, ISP. LANXESS, TROY)
B7.1.1/02 Submitted with the PT6 BPD dossier	Klamer, M. Morsing, N.	2006	Leaching of active ingredients from preservative treated wood in storage situations Source: Danish Technological Institute, Toastrup, The Netherlands Report No.: 1006657-02-22 Not GLP; (unpublished) Doc. No.: 732-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation