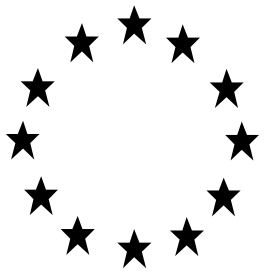
Directive 98/8/EC concerning the placing of biocidal products on the market

Inclusion of active substances in Annex I or IA to Directive 98/8/EC

Assessment Report



IPBC

Product-type 8
(Wood Preservatives)

22 February 2008

Annex I - DK

IPBC (PT 8)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 22 February 2008 in view of its inclusion in Annex I to Directive 98/8/EC

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of IPBC as product-type 8 (Wood preservatives), 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 a view to the possible inclusion of this substance into Annex I or IA to the Directive.

IPBC (CAS no. 55406-53-6) was notified as an existing active substance, by the members of the European Union IPBC Task Force (Arch Chemicals, LANXESS Deutschland GmbH, Sostram Corp., Troy Corp.), c/o SCC GmbH, hereafter referred to as the applicant, in product-type 8. From 14 February 2008, Dow Benelux B.V. replaced Sostram Corp. in that task force.

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 8 was 28 March 2004, in accordance with Article 9(2) of Regulation (EC) No 1451/2007.

On 28 March 2004, the Danish competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 28 September 2004.

On 29 September 2006, 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 4 October 2006. The competent authority report included a recommendation for the inclusion of IPBC in Annex I to the Directive for product-type 8.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 20 December 2006. 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

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

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

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

On the basis of the final competent authority report, the Commission proposed the inclusion of IPBC in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 22 February 2008.

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 22 February 2008.

1.2. Purpose of the assessment report

This assessment report has been developed and finalised in support of the decision to include IPBC in Annex I to Directive 98/8/EC for product-type 8. The aim of the assessment report is to facilitate the authorisation in Member States of individual biocidal products in product-type 8 that contain IPBC. In their evaluation, Member States shall apply the provisions of Directive 98/8/EC, in particular the provisions of Article 5 as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available at the Commission website[3], shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Directive 98/8/EC, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

1.3. Overall conclusion in the context of Directive 98/8/EC

The overall conclusion from the evaluation is that it may be expected that there are products containing IPBC for the product-type 8, which will fulfil the requirements laid down in Article 5 of Directive 98/8/EC. This conclusion is however subject to:

i. compliance with the particular requirements in the following sections of this assessment report,

ii. the implementation of the provisions of Article 5(1) of Directive 98/8/EC, and

iii. the common principles laid down in Annex VI to Directive 98/8/EC.

Furthermore, these conclusions 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 Article 5(1) and of the common principles laid down in Annex VI to Directive 98/8/EC.

3 http://ec.europa.eu/comm/environment/biocides/index htm

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

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

Identity

IPBC, CAS No. 55406-53-6, is a fungicide produced by Arch Chemicals, LANXESS Deutschland GmbH, Sostram Corp., Troy Corp. sites in USA and 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, LANXESS Deutschland GmbH, Sostram Corp.4, 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 2.36-4.5E-03 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 is 2.81 at 25°C.

The substance is stable at room temperature and is stable at 54^{o}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 and water with the respective limits of quantification of 10 µg/kg of soil and 0.1 µg/l of water.

Residues in air were not necessary because IPBC is not volatile and spray applications only involve non-respirable particles.

4 From 14 February 2008, Dow Benelux B.V. replaced Sostram Corp. in that task force.

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 contact with food or feedstuffs.

2.1.2. Intended Uses and Efficacy

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

In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

2.1.3. Classification and Labelling

Proposed classification/labelling 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 S2 S22 S24 S26 S37/39 S38 S45 S46	Keep locked up. Keep out of the reach of children. Do not breath dust. Avoid contact with skin. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable gloves and eye/face protection. In case of insufficient ventilation, wear suitable respiratory equipment. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). If swallowed, seek medical advice immediately and show this container or label.
	S61	Avoid release to the environment. Refer to special instructions/Safety data sheets.

However, there is still an outstanding question about risk phrase 53. As no common agreement between the Member States could be achieved this question will be sent to the Classification and Labelling group for clarification.

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 solvent-based formulations containing 0.6, 2.3, and 17.1% IPBC, 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 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 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.

For the AOEL-setting two scenarios are expected. Professional and industrial operators would be expected to have regular exposure to IPBC (chronic exposure). Amateurs are considered to be exposed for a shorter period of time (once or twice a year). Secondary exposure can be either of short or of long duration. Considering the exposure situation with IPBC it is appropriate to deviate from the normal default procedure of establishing only one AOEL. Consequently, two very different exposure scenarios should be considered long-term exposure and short-term exposure.

Therefore two different values will be used as basis for the risk characterisation:

The $AOEL_{long\text{-}term}$ 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 AOEL setting.

AOEL$_{long\text{-}term}$= 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 AOEL$_{short\text{-}term}$ 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.

AOEL$_{short\text{-}term}$= 35 mg/kg bw/day / 100 = 0.35 mg/kg bw/day

Based on the exposure situation and expected exposure time durations (amateur use estimated to be 1-2 days/year) and the toxicological profile of the active substance (where the critical effects are due to repeated exposure) are an acute AOEL is not justified. The AOEL for short-term exposure (0.35 mg/kg bw/day) could also cover potential acute exposure as a conservative approach

2.2.1.3 Exposure assessment

The exposure to humans is estimated for the majority of the intended uses of wood preservatives containing IPBC. The tasks foreseen in primary exposure are for Industrial users: double-vacuum and vacuum-pressure impregnation, supercritical CO_2, dipping, flow-coating and automated spraying for Professional users: injection, brush painting and manual spraying and for Non-professional users: only brush painting and spraying.

The estimations of the primary industrial exposure are based on the assumption that the content of IPBC in the products used for the application phase is maximum 0.8% w/w, while the concentration of active substance (a.s.) in the products used for mixing and loading is maximum 8% w/w. However, the model product contains an in-use concentration of 0.7% w/w IPBC and this exact value is typically not represented in the risk calculations. Therefore, the acceptable uses will be based on the in-use concentrations reflected in the different exposure assessment calculations. Exposure assessment was done on the basis of a solvent-based and a water-based model product/guide recipe.

The potential secondary exposure is addressed in the following scenarios: for adults sanding treated wood posts by the inhalation route (acute and chronic), for infants chewing wood off-cut, children playing on playground structure outdoors and infants playing on weathered (playground) structure and mouthing (dermal and ingestion). In addition a scenario for adults, infants and children taking into account chronic exposure to wood preservatives which may arise from indoor remedial treatment (inhalation of volatilised residues indoors) was presented.

All calculations were performed according to the recommendations of the TNsG – Human Exposure to Biocidal Products (2002). In the model calculation, it is assumed that the 75th percentile from the measured data given in the TNsG represents a reasonable scenario for risk assessment purposes. The default value for body weight of an exposed person is assumed to be 70 kg. The use of a 60 kg body weight will not change the outcome of the risk characterization. For the product authorisation the value of 60 kg should be used.

2.2.1.4 Risk characterisation

The risk characterisation revealed that the highest exposure occurs in industrial and professional uses and comes from vacuum pressure, brushing, dipping, flow-coat and automated spraying. Double vacuum, injection and supercritical CO2 technique result in lower exposure. Exposure during manual application (spraying, injection) either by professionals or by amateur is comparable to the exposure resulting from industrial uses of IPBC.

The exposure assessment for primary exposure showed that the risk for the industrial operator up to and including the maximum in-use concentration during treatment of wood with double vacuum, vacuum pressure and supercritical CO2 is acceptable. The maximum in-use concentrations were 0.6 %, 0.09% and 0.015% IPBC for double vacuum, vacuum pressure and supercritical CO2, respectively.

For dipping, flow-coat, and automated spraying technique in-use concentrations of 0.8% IPBC resulted in acceptable exposure levels for the professional operator.

Table 2.2-1

Primary exposure industrial use				
Exposure scenario Intended use	**PPE**	**In-use concentration [% IPBC]**	**% of AOEL $_{long\ term}$**	**MOE**
Double vacuum	gloves	0.6	9.9	1000
Vacuum pressure	gloves	0.09	63.7	157
Supercritical CO_2	gloves	0.015	0.9	10000
Dipping	gloves	0.3-0.8	54.9	146
Flow-coat	gloves	0.5-0.8	54.9	181
Automated spraying	gloves	0.2-0.8	54.9	181
Primary exposure professional use				
Manual spraying	gloves	0.2	29.6	350
Brushing	gloves	0.5	15.5	666
	gloves	1,4	43.4	222
Injection	gloves	0.05	3.8	2500
Primary exposure amateur use				
Spraying outdoors	bare hands	0.2	30.3	330
Brushing outdoors	no gloves	0.5	13.9	700
		1.4	39.0	250

The primary exposure both for industrial, professional and non-professional uses of IPBC does not exceed the AOEL long-term of 0.2 mg/kg bw/day or AOEL short-term of 0.35 mg/kg bw/day (for amateurs). The calculated MOE ratios were all greater than 100. Thus, the risk for the operator during double vacuum, vacuum pressure, supercritical CO2, dipping, flow-coat, injection, brushing and automated/manual spraying processes is considered to be acceptable.

The potential secondary exposure is addressed in the following scenarios: for adults sanding treated wood posts by the inhalation route (acute and chronic), for infants chewing wood off-cut, children playing on playground structure outdoors and infants playing on weathered (playground) structure and mouthing (dermal and ingestion). In addition a scenario for adults, infants and children taken into account chronic exposure to wood preservatives which may arise from indoor remedial treatment (inhalation of volatilised residues indoors).

The risk during secondary exposure to IPBC is considered to be acceptable because the respective AOELs for long- and short-term exposure are not exceeded and the calculated MOE ratios were greater than 100.

The risk assessment is in general based on the assumption that the products are used according to the conditions for normal use. It is furthermore assumed that the recommended personal protective equipment (PPE) will always be worn by industrial and professional users.

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 used in wood preservatives 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 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^{o}C. IPBC is metabolised rapidly in soil in laboratory experiments, the half-life is estimated to be 4.7 hour at 12^{o}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. Iodine will be evaluated by SE as an active substance for disinfectant and an effect and risk assessment will therefore not be performed here.

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. Effects assessment

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

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

The toxicity to terrestrial organisms is documented by acute studies. 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:

$PNEC_{water}$ = 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 wet soil/1000 = 0.005 mg/kg wet 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. Therefore an exposure assessment and risk assessment on PBC is not considered further. 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 assessment

IPBC does not fulfil the PBT or vPvB criteria.

2.2.2.4. Exposure assessment

PEC in surface water

The OECD ESD guidance available is limited to local exposure calculations for wood preservative life-cycle stages of product ´application` and ´wood in-service` only. Therefore the assessment has primary determined local concentrations for these life-cycle stages. No determination of regional concentrations has been made, since the wood preservative uses outlined are not considered to be of sufficiently large scale. Due to the many different

applications of IPBC nearly all respective OECD models for application, storage and use were calculated.

Application and storage

These scenarios cover industrial applications and storage.

For the application stage (e.g. vacuum pressure treatment, or flow coating) it is assumed that - depending on the physical-chemical properties of the compound a certain amount of the applied active substance will enter the surface water via a waste water treatment plant. The estimated exposure from the effluent of the STP is based on PBC concentrations. The concentrations will be based on the IPBC concentrations in the influent and with no removal process in the STP except for iodine. In the application scenarios a PBC concentrations in surface water between 0.75 µg/l and 36.4 µg/l are calculated from the models.

For the storage stage it is assumed in the OECD models that emissions from the storage place directly reach a small creek. Calculated IPBC concentrations in surface water were between 0.9 and 4.44 µg/l.

In-situ treatment

During outdoors in situ treatment an initial PEC can be calculated according to an OECD model. The OECD model covers a wooden bridge over a small pond. Assuming a 3% (professionals) or 5% (amateurs) emission of the applied product into water, initial PECs for the guide recipe containing 0.7% IPBC are calculated. The initial PECs in water resulting from the models were 9.45 and 33 µg/l for a water based and a solvent based formulation, respectively for professionals and 15.8 and 55 µg/l for amateurs (for a water based and solvent based formulation, respectively). These initial concentrations in water will be reduced after 30 days by taking into account the degradation. Thus after 30 days the PEC water was negligible for both professionals and amateurs. Already 2 days after application the concentration will be negligible (less than 0.0002 µg/l and 0.0004 µg/l, for professionals and amateurs, respectively for the water based formulation). For the solvent based formulation the concentrations were 9×10^{-4} µg a.s./l and 2×10^{-3} µg a.s./l after 2 days for professionals and amateurs, respectively.

Outdoor service life

The OECD model “bridge over a small pond” calculates concentrations in pond water after 30 days and a longer relevant time period after application. Applying this scenario and taking into account a half-life of 0.129 days in the surface water, concentrations in water after 30 days was between 0.3µg/l and 2.5 µg/l. The highest value of 2.5µg/l rapidly decreases to 1 µg/l after 100 days. The corresponding values were between 0 and 0.03 µg/l after a relevant longer time period depending on the specific emission rates.

The OECD model “noise barrier” assumes that one third of the emissions from wood will reach the sewage and – via STP - the surface water. Depending on the application specific emission rates from wood for this scenario, concentrations of PBC in surface water after the first 30 days were between 0.16 and 1.5 µg PBC/l. After the longer time period the corresponding values were 0.003–0.05 µg/l). The estimation of the PBC concentration is based on 100% transfer of IPBC to PBC in the STP and no further degradation of PBC in the STP.

The OECD model “bridge over a small pond” calculates the realistic worst case concentrations after brushing (in-situ treatment) in pond water 30 days and a TIME 2 after application. The PEC calculations have been made after 30 days and after 5 years after application. Applying this scenario the amount of IPBC from in situ treatment (amateurs) for the 30 days situation is between 397 µg/l and 191 µg/l in surface water for a water and solvent based formulation, respectively (without taken into account the amount from application which is considered negligible, and as a first step not taken the degradation in water into consideration). The corresponding values taken degradation into consideration were 2.5 µg/l and 1.2 µg/l for water and solvent based formulation, respectively.

Applying the same scenario for the 5 years situation the concentrations in water is between 730 µg/l and 365 µg/l for a water and a solvent based formulation, respectively (without taken degradation into consideration). The corresponding values taken degradation into consideration were 0.07 µg/l and 0.04 µg/l for water and solvent based formulation, respectively.

PEC in sediment

The calculation of the PEC for the sediment is not relevant as there are no specific data for determinations the PEC, and also no data on sediment dwelling organisms. Therefore the risk assessment for sediment based on the equilibrium method will give the same results as that for surface water.

PEC in air

Not relevant due to the low vapour pressure of the active substance.

Results indicate that emissions of IPBC are extremely low. Based on the physico-chemical properties of IPBC including a estimated tropospheric half-life of 5 hours for a 12 h day (15 hours for a 24 h day) this issue will not be considered further.

PEC in soil

According to the OECD models for IPBC used in wood preservation, PECs in soil are calculated for different situations:

Application and storage

Emissions into soil are assumed to occur during outdoor storage of the treated wood. It is assumed in the OECD models, that emissions from the storage place reach the soil directly. Calculated IPBC concentrations in the soil of the storage places were between 0.03 and 0.24 mg IPBC/kg wet soil after 30 days and 0.03 and 0.24 mg IPBC/kg wet soil after 20 years, taking into account degradation in soil and depending on the application-specific emissions rates.

In-situ treatment

During outdoors in-situ treatment, an initial PEC can be calculated according to the OECD models. The OECD models cover outdoor brushing of a timber house. Assuming a 3% (professionals) or 5% (amateurs) emission of the applied product into soil, initial PECs for the guide recipe containing 0.7% IPBC were calculated. These initial (just after application) PECs

in soil resulting from the house scenario model were 2.8 and 9.7 mg IPBC/kg wet soil for a water and solvent based formulation, respectively for professionals. For amateurs these values were 4.6 and 16.2 mg IPBC /kg wet soil for a water and solvent based formulation, respectively. After 30 days the concentrations of IPBC in soil were negligible (for the water based formulation the concentration was calculated to 2.25×10^{-45} mg/kg and 3.75×10^{-45} mg/kg for professionals and amateurs, respectively). It should also be mentioned that these values are based on a 10 cm distance from the house as described in the ESD and these values will be even lower when based on a distance of 50 cm. The initial concentration of IPBC in soil could be considerably mitigated by covering the particular soil area with protective foil or paper.

Outdoor service life - HC 3

For use (hazard) class 3 out door service life the OECD models “timber house” and "noise barrier” was applied. Soil concentrations were calculated for 30 days and a relevant long service time after application taking into account a half-life of IPBC in soil.

The highest soil concentrations were reached in the timber house scenario (0.1–1.1 mg IPBC/kg wet soil after 30 days and 0.001–0.03 mg /kg wet soil after a relevant longer time period, taking into account degradation of IPBC in soil and depending on the application-specific emission rates). The highest concentration was found in the timber house scenarios related to brushing.

The OECD model “noise barrier” assumes that 2/3 of the emissions from wood will reach the soil. The calculated PECs are considerably lower than in the timber house scenario.

Receiving soil volume

In all model calculations the receiving soil compartment was based on default compartment assuming 10 cm distance and depth from the treated wood. However, as agreed at CA level a 50 cm distance will be based for the risk assessment. Therefore for a refined assessment an enlarging of the receiving soil volume was done. Increasing the distance from the treated wood both with respect to the horizontal and lateral distance enlarged the receiving soil compartment. The calculations were done for 20, 30, 40 and 50 cm distance and depth resulting in an enlargement of the receiving soil volume by a factor of 4 (20 cm), 9 (30 cm), 16 (40 cm) and 25 (50 cm).

Non-compartment-specific exposure relevant to the food chain (secondary poisoning)

A secondary exposure of man to IPBC relevant to the food chain can be excluded due to the minimum amount which reaches the soil. In addition, the log K_{ow} is less than 3 and the soil area of concern is very small.

PBC as a relevant metabolite

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.

PEC groundwater

For the industrial treatment plants (storage sites) no IPBC or PBC is expected in the ground water during the first year. However, due to the long continuous exposure a risk for the ground water can not be excluded after a few years

The fate and behaviour for IPBC suggest that it is not expected to reach groundwater during outdoor service life of treated wood since this compound has been shown to have a T½ of 0.196 days in soil at 12°C. Therefore an exposure assessment for groundwater on IPBC is not considered further for the use phase.

2.2.2.5. Risk characterisation

Aquatic Compartment

Risk assessments which take into account the degradation of IPBC from the water are considered the most appropriate and are therefore used.

For industrial application the PEC:PNEC values for surface water was unacceptable (> 1) for most industrial applications facilities due to the direct run off from the storage places; however no risk was identified from the industrial application methods itself.

For *in situ* applications, the risk was evaluated for brushing of a bridge over a small pond. The risk was acceptable for both professionals and amateurs after both 30 days and after a longer time period.

For wood in service a risk was found for most applications but only after 30 days. At TIME 2 (5, 15 or 20 years) all the PEC/PNEC risk quotients are below one. For in-service life, the risk identified for most scenarios after 30 days shall be accepted because it is expected to be for a short period of time.

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

Terrestrial compartment

The risk posed to the local soil compartment within industrial wood treatment sites is not acceptable. This risk shall therefore be mitigated e.g. by restricting the storage of industrial

treated timber to hard standing (preventing the direct losses to soil) and collecting rain water from the storage area. This is currently considered good practice in many Member States.

For the industrial treatment plants (storage sites) no IPBC or PBC is expected in the ground water during the first year. However, due to the long continuous exposure a risk for the ground water can not be excluded after a few years and risk reductions might be necessary. In any case risk reduction measurement at the storage sites like covering the soil has to done as there is found a risk for both the soil and surface water. These risk reductions measurement will also prevent potential contamination of the ground water.

The PEC:PNECs produced during the *in situ* application scenarios for wood out of ground contact is less than 1 after 30 days and decrease further during time. Furthermore covering the ground surrounding the object to be treated with protective foil can drastically reduce the emissions during *in situ* treatment.

When the risk assessment for in-service life is performed according to the present OECD environmental emission scenario the risk to soil was unacceptable for nearly all the applications in HC 3 after 30 days. A significant reduction of the risk was seen at TIME 2. At this time a risk was found only for surface treated wood and even here no risk was found if the distance from the treated wood was increased to 30 cm.

During the discussion with the Commission and the other Member States after the submission of the draft Competent Authority Report it has been agreed that a risk can be accepted after 30 days for substance where it is documented that the PEC/PNEC ratio will decrease with time. Therefore the evaluation should focus on the Time 2 period. Furthermore it was agreed at the CA-meeting in November 06 that the distance should be increased to 50 cm. For substance where a risk is identified at that distance, additional risk mitigation measures wood need to be taken at product level to bring the risk down at 50 cm. However, such substances would not to be automatically excluded from Annex I based on the leaching distance but the Annex I inclusion should flag if the 50 cm distance was exceeded. If a risk is identified then a specific provision should be added to indicate that in the view of the risk identified for the soil compartment appropriate risk mitigation measures must be taken to protect that compartment. For IPBC no risk has been identified during use of the treated wood and therefore no specific risk mitigation has been suggested.

Disposal of IPBC treated wood

It is most unlikely that IPBC from treated timber will result in an environmental risk during incineration under controlled conditions; however other ingredients in a formulation may result in an environmental risk during incineration of treated timber. Therefore special focus on this life-cycle stage has been deferred to the Member State assessment at the product authorisation stage. The risk of iodine when the treated wood is incinerated is not considered as a major problem assuming BAT. Humans add iodine gas to the air, by burning coal or fuel oil for energy, or impregnated wood. The amount of iodine that enters the air through human activity is fairly small compared to the amount that vaporizes from the oceans. The risk from a normal landfill site is assumed to be lower than that described for the house scenario for wood in service because the emission from impregnated wood per m^2 soil is assumed to be smaller. However, if impregnated wood is collected specifically and disposed in special areas of a landfill it is assumed that special precaution has been taken for this part of the landfill.

2.2.3. List of endpoints

In order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the most important endpoints, as identified during the evaluation process, are listed in Appendix I.

3. DECISION

3.1. Background to the Decision

The overall conclusion from the evaluation of IPBC for use in Product Type 8 (Wood Preservatives), is that it may be possible for Member States 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.

Assessed from the documentation for the active substance, IPBC, and the representative biocidal products containing 0.7% w/w IPBC (concentration in the model formulations), the proposed manner and areas of use of products intended to control wood disfiguring and wood-rotting fungi may be sufficiently effective for these uses and without unacceptable risk either to human health or to the environment. Furthermore, the evaluation of the risks for humans and the environment originating in exposure for IPBC from impregnated wood resulted in the overall conclusion that the manner and areas of the proposed uses were acceptable.

However, certain mitigation measures are required as a condition of use of wood preservatives containing IPBC in order to remove those concerns that have been identified in the risk assessment for 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 the normal use recommended on the label of the product.

3.2. Decision regarding Inclusion in Annex I

The IPBC shall be included in Annex I to Directive 98/8/EC as an active substance for use in product-type 8(wood preservatives), subject to the following specific provisions:

Member States shall ensure that authorisations are subject to the following conditions:

(1) In view of the assumptions made during the risk assessment, products authorised for industrial and/or professional use, must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means

(2) In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.

3.3. Elements to be taken into account by Member States when authorising products

Products containing IPBC have been evaluated for the used to control wood-rotting fungi by impregnation of wood for use up to hazard class 3 for all application methods.

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

1. Vacuum pressure; maximum retention: 0.04 kg/m^3
2. Supercritical CO_2; maximum retention: 0.06 kg/m^3
3. Double vacuum; maximum retention: 0.06 kg/m^3
4. Automated spraying; maximum retention: 1.20 g/m^2
5. Flow coating; maximum retention: 1.00 g/m^2
6. Dipping and spraying; maximum retention: 2.22 g/m^2
7. *In situ* outdoors brush painting; maximum retention: 2.20 g/m^2

- When Member States are authorising products, both the application methods and the nature of the product including concentrations of the active components and of the non-active components within the product must be considered, since these factors could affect e.g. the leaching rate of these substances from the treated wood, the (eco)toxicity and the overall classification of the product.

- The efficacy of individual products must be demonstrated prior to product authorisation at the Member State level.

- It is most unlikely that IPBC from treated timber will result in an environmental risk during incineration under controlled conditions; however other active substance in a formulation may result in an environmental risk during incineration of treated timber. Therefore special focus on this life-cycle stage has been deferred to the Member State assessment at the product authorisation stage.

In the treatment of wood, Member States shall ensure that:

- Where direct losses to water are possible products showing a PEC:PNEC ratio of more than 1 appropriate risk mitigation measures are taken to protect the water compartment.

- Appropriate risk mitigation measures are taken when treated timber with a formulation of IPBC shows a PEC/PNEC ratio of more than 1.

According to the EU waste legislation waste from wood preservative products and application solutions are considered hazardous waste. Therefore, application solutions must be collected and reused or disposed of as hazardous waste and they must not be released to soil, surface water or any kind of sewer[5].

5 These requirements may actually be determined in detail in the environmental permits of the application plants on the basis of the Council Directive 96/61/EC on Integrated Pollution Prevention and Control (IPPC) but should be listed in the instructions for use of a biocidal product.

Impregnated wood must not come in contact with food or feedstuffs.

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 inclusion of IPBC in Annex I to Directive 98/8/EC.

However, an analytical method for the detection and identification of IPBC in animal and human body fluids and tissues has to be submitted at the product evaluation stage.

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 referred to in Articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the inclusion of IPBC in Annex I to the Directive.

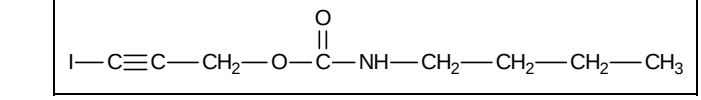
Appendix I: List of endpoints

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	maxima at 191 nm and 227 nm

state ε at wavelength)	
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.

Summary of intended uses for IPBC-based wood protection products (PT8)

Object and/or situation (a)	Member State or Country	Product name (j)	Organisms controlled (c)	Formulation		Application			Applied amount	
				Type (d-f)	Conc. of as [% IPBC] (i)	method kind (f-h)	number per year or per lifetime of wooden structure (k)	interval between applications (min)	g as/L not relevant for model formulations	water L/m not relevant model formulation
Wood preservation	EU	n.a.	Rotting and disfiguring fungi	s.b.	0.7	Double vacuum	1	1 application per lifetime	n. r.	n. r.
Wood preservation	EU	n.a.	Rotting and disfiguring fungi	w.b.	0.7	Double vacuum	1	1 application per lifetime	n. r.	n. r.
Wood preservation	EU	n.a.	Rotting and disfiguring fungi	--	0.7	Super-critical CO2	1	1 application per lifetime	n. r.	n. r.
Wood preservation	EU	n.a.	Rotting and disfiguring fungi	w.b.	0.7	Vacuum pressure	1	1 application per lifetime	n. r.	n. r.
Wood preservation	EU	n.a	Rotting and disfiguring fungi	s.b.	0.7	Auto-mated spraying	1	1 application per lifetime	n. r.	n. r.
Wood preservation	EU	n.a.	Rotting and disfiguring fungi	w.b.	0.7	Auto-mated spraying	1	1 application per lifetime	n. r.	n. r.
Wood preservation	EU	n.a.	Rotting and disfiguring fungi	w.b.	0.7	Flow coat	1	1 application per lifetime	n. r.	n. r.
Wood preservation	EU	n.a.	Rotting and disfiguring fungi	s.b.	0.7	Flow coat	1	1 application per lifetime	n. r.	n. r.
Wood preservation	EU	n.a.	Rotting and disfiguring fungi	w.b.	0.7	Dipping	1	1 application per lifetime	n. r.	n. r.
Wood preservation	EU	n.a	Rotting and disfiguring fungi	s.b.	0.7	Dipping	1	1 application per lifetime	n. r.	n. r.
Wood preservation	EU	n.a.	Rotting and disfiguring fungi	w.b.	0.7	Brushing	1	1 application per lifetime	n. r.	n. r.

Object and/or situation (a)	Member State or Country	Product name (j)	Organisms controlled (c)	Formulation		Application			Applied amount p	
				Type (d-f)	Conc. of as [% IPBC] (i)	method kind (f-h)	number per year or per lifetime of wooden structure (k)	interval between applications (min)	g as/L not relevant for model formulations	water L/m not relevant model formulation
Wood preservation	EU	n.a.	Rotting and disfiguring fungi	s.b.	0.7	Brushing	1	1 application per lifetime	n. r.	n. r.
Wood preservation	EU	n.a.	Rotting and disfiguring fungi	s.b.	0.7	Spraying /brushing	1	< =1 application per year	n. r..	n. r.
Wood preservation	EU	n.a.	Rotting and disfiguring fungi	w.b.	0.7	Spraying /brushing	1	< =1 application per year	n. r.	n. r.
Wood preservation	EU	n.a.	Rotting and disfiguring fungi	w.b.	0.7	Injection in holes	1	< =1 application per year	n. r.	n. r.
Wood preservation	EU	n.a.	Rotting and disfiguring fungi	s.b.	0.7	Injection in holes	1	< =1 application per year	n. r.	n. r.
Wood preservation	EU	n.a.	Rotting and disfiguring fungi	w.b.	0.7	Brushing	1	n.a.	n. r.	n. r.
Wood preservation	EU	n.a.	Rotting and disfiguring fungi	s.b.	0.7	Brushing	1	n.a.	n. r.	n. r.
Wood preservation	EU	n.a.	Rotting and disfiguring fungi	w.b.	0.7	Spraying /brushing	1	< =1 application per year	n. r.	n. r.

(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) IPBC concentration in model formulations (j) n a not applicable (model formulations described in the Dossier); w b water based formulation; s-b-: solvent-based formulations

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)	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)	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)	AM in body fluids and tissues to be submitted at the product evaluation stage.
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not necessary, IPBC-based wood preservation products or materials treated with such products are not used in a manner which may cause contact with such materials.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	Not necessary, IPBC-based wood preservation products or materials treated with such products are not used in a manner which may cause contact with such materials.

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, 10, and 30% for solutions containing 17, 2.4 and 0.6% IPBC 100% default for solutions containing <0.5%-0.6% IPBC (based on *in vitro* human skin study with solvent based

	model products)
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	> 2,000 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 inhalation NOAEL	1.16 mg/m^3 (90-day inhalation study in rats) R37 : Irritating to respiratory system

Genotoxicity (Annex IIA, VI.6.6)	No evidence for a genotoxic potential in *in vitro* and *in vivo* tests.

Carcinogenicity (Annex IIA, VI.6.7)

Species/type of tumour	Non-carcinogenic 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	Maternal: 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
$AOEL_{long\ term}$ (Operator/Worker Exposure) –	0.2 mg/kg bw/day	2-years rats study	100
$AOEL_{short\ term}$ (Operator/Worker Exposure) –	0.35 mg/kg bw/day	90-day gavage rat study	100
*AOEL (Operator/Worker Exposure)	0.35 mg/kg bw/day	90-day gavage rat	100

– acute		study	
Drinking water limit	Limit for pesticides in the Drinking Water Directive is 0.1 µg/l, no other value will be calculated.	-	-
ARfD (acute reference dose)	Not relevant	--	--

* Based on the exposure situation and expected exposure time durations (amateur use estimated to be 1-2 days/year) and the toxicological profile of the active substance (where the critical effects are due to repeated exposure) an acute AOEL is not justified for IPBC used in PT8. The AOEL for short-term exposure (0 35 mg/kg bw/day) could also cover potential acute exposure as a conservative approach.

Acceptable exposure scenarios (including method of calculation)

Professional users	No risk identified for proposed uses with the representative model product with in use concentration of 0.7% IPBC (according to models provided by the TNsG of Human Exposure[1)]).
Non-professional users	No risk identified for proposed uses with the representative model product with in use concentration of 0.7% IPBC (according to models provided by the TNsG of Human Exposure[1)]).
Indirect exposure as a result of use	No risk identified for proposed uses with the representative model product with in use concentration of 0.7% IPBC (according to models provided by the TNsG of Human Exposure[1)]).

[1)] Technical Notes for Guidance – Human Exposure to Biocidal Products – Guidance on Exposure Estimation (June 2002)

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.
Biodegradation in seawater	Since IPBC-based products are only intended for Hazards classes 2 and 3, direct exposure of the aquatic compartment does not take place. Therefore, a study on biodegradation in seawater is not required.
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 30 hours at 12°C
DT_{90} total systems (sterile)	44.3 hours at 22°C 99 hours at 12°C
	PBC:
DT_{50} total systems (nonsterile)	11.5 days at 22°C 26 days at 12°C
DT_{90} total systems (nonsterile)	38.4 days at 22°C 86 days at 12°C

Mineralization (nonsterile)	Mineralization is 10% after 120 days
Mineralization (sterile)	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.
Distribution in water / sediment systems (metabolites)	**Propargyl butyl carbamate (PBC)**: Surface water: up to ca. 88.6 % PBC (8 hours) Sediment: up to ca. 13.3 – 20.9 % (4 hours/Day 1) **2-propenyl butyl carbamate (2-PBC):** Surface water: up to ca. 34.7 – 35.9 % (Day 59) Sediment: up to ca. 8.0 – 8.8 % (Day 59/Day 93)

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): 5 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)
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 7 days which is the maximum value (nonsterile, 22°C, n = 1) 9.6 % AR after 28 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 DT50 (12°C calculated according to Arrhenius) = 10 days.

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) Koc (HPLC method): 126 (log Koc = 2.1)
pH dependence (yes / no) (if yes type of dependence)	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 = 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 8
Acute toxicity to birds (Annex IIIA, point XIII.1.1)	Not required for Product type 8
Dietary toxicity to birds (Annex IIIA, point XIII.1.2)	Not required for Product type 8
Reproductive toxicity to birds (Annex IIIA, point XIII.1.3)	Not required for Product type 8

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

Acute oral toxicity	Not required for Product type 8
Acute contact toxicity	Not required for Product type 8

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

Acute oral toxicity	Not required for Product type 8
Acute contact toxicity	Not required for Product type 8
Acute toxicity to ……..	Not required for Product type 8

Bioconcentration (Annex IIA, point 7.5)

Bioconcentration factor (BCF)	Not relevant for IPBC
Depration time (DT_{50}) (DT_{90})	Not relevant for IPBC

Level of metabolites (%) in organisms accounting for > 10 % of residues	Not relevant for IPBC

Chapter 6: Other End Points

Not applicable, no other end points

Appendix II: List of Intended Uses

IPBC has been evaluated for its use in wood preservation (Product Type 8 of the Biocidal Products Directive) up to and including Hazard Class 3[5]. It is applied in both solvent- and water based formulations and can be applied by industrial as well as professional and amateur user.

Products can be used for:

- The pre-treatment of timber (dipping, automated spraying, flow coat, double vacuum, supercritical CO_2, and vacuum pressure by industrial/professional users); and
- The protective treatment of wood *in situ* by injection in holes and in brush application (both professional and amateur users)

Model products for two representative biocidal products (a water-based and a solvent-based formulation) were submitted by the Applicant – both containing 0.7% w/w IPBC.

The representative effective retention in wood in kilogram or g a.s./m^2 or a.s./m^3 for the field of use envisaged and which has been evaluated:

- Vacuum pressure, 0.04 kg/m^3
- Supercritical CO_2 0.06 kg/m^3
- Double vacuum 0.06 kg/m^3
- Automated spraying 1.20 g/m^2
- Flow coating 1.00 g/m^2
- Dipping, and brushing 2.20 g/m^2

These values were provided, accepted in support of these intended uses and used in the environmental risk assessment.

Appendix III: List of studies

Data protection is claimed by the applicant in accordance with Article 12.1(c) (i) and (ii) of Council Directive 98/8/EC for all study reports marked "Y" in the "Data Protection Claimed" column of the table below. For studies marked Yes(i) data protection is claimed under Article 12.1(c) (i), for studies marked Yes(ii) data protection is claimed under Article 12.1(c) (ii). These claims are based on information from the applicant. It is assumed that the relevant studies are not already protected in any other Member State of the European Union under existing national rules relating to biocidal products. It was however not possible to confirm the accuracy of this information.

Doc IIA **Section No./ Reference No.**	**Author(s)**	**Year**	**Title** **Source (laboratory)** **Report No.** **GLP; (un)published** **Doc. No.**	**Data protection**	**Owner**
A4.2a/01	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, SOSTRAM, TROY)
A4.2c/01	Bruckhausen, P.	2004	Development and validation of the residue analytical method for the determination of IPBC and its 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, LANXESS, SOSTRAM, TROY)
A5.3.1/01	Briscoe, P.A. Williams, G.R. Anderson, D.G. Gadd, G.M.	1990	Microbial tolerance and biodetoxication of organic and organometallic biocides Source: IRG Secretariat Sweden Report No.: IRG/WP/1464 Not GLP; (published) Doc. No.: 392-011	No	N.R.
A5.3.1/02	Hansen, J.	1984	IPBC - A new fungicide for wood protection Source: IRG Secretariat Sweden Report No.: IRG/WP/3295 Not GLP; (published) Doc. No.: 392-002	No	N.R.
A6.1.1/01	XXXX	2000	Preventol MP 100 - Acute oral toxicity study in male and female wistar rats Source: XXXX Report No.: XX 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	XXXX	2000	Preventol MP 100 - Acute dermal toxicity study in male and female wistar rats Source: XXXX Report No.: XXX30454 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	XXXX	1985	Acute inhalation limit test in rats 3-iodo-2-propynyl butyl carbamate Source: XXXX USA 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	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
A6.1.3	XXXX	1994	Acute inhalation toxicity in rats 4-hour exposure to Omacide IPBC Source: XXXX Report No. XX 5/931809 GLP; (unpublished) Doc. No. 523-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A6.1.4/01	XXXX	2000	Acute skin irritation test (patch test) of Preventol MP 100 in rabbits Source: XXXX Report No.: XX 7891 9300/450/95 T8069193 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

Doc IIA **Section No./ Reference No.**	**Author(s)**	**Year**	**Title** **Source (laboratory)** **Report No.** **GLP; (un)published** **Doc. No.**	**Data protection**	**Owner**
A6.1.4/02	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.)	SOSTRAM Corporation
A6.1.5/01	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.)	SOSTRAM Corporation
A6.1.5/02	XXXX	1993	TROYSAN Polyphase P-100 - The guinea pig maximization test Source: XXXX Report No.: XX 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	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.: XX 30653 T5069983 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
A6.1.5	XXXX	1993	Delayed contact dermal sensitization (Buehler method) Source: XXXX Report No.: XX 92-2193 F GLP; (unpublished) Doc. No.: 567-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A6.1.5	Shimizu, Yamano, Noda	2000	Allergenicity evaluation of chemicals for use in household products (IV) – Contact allergenicity of three halide bactericides, 3-iodo-2-propynyl butylcarbamate (IPBC), p-chlorophenyl –3-iodopropargylformyl (CPIP) and BECDIP in guinea pigs Not GLP; (published) Doc. No. 592-008	No	N.R.
A6.1.5	Zissu, D.	2002	The sensitizing potential of various biocides in the guinea pig maximization test Source: Contact Dermatitis 2002, 46, 224-227 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-012	No	N.R.
A6.2/01	XXXX	1995	Metabolism of 14C-IPBC in rats Source: XXXX Report No.: XX 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	XXXX	1995	The in vitro percutaneous absorption through human abdominal epidermis of [14C]-IPBC (3-Iodo-2-Propynyl-N-Butyl-Carbamate) Source: XXXX Report No.: 155046 12367 TC0510 GLP; (unpublished) Doc. No.: 511-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.3.1/01	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.: XX 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

Doc IIA **Section No./ Reference No.**	**Author(s)**	**Year**	**Title** **Source (laboratory)** **Report No.** **GLP; (un)published** **Doc. No.**	**Data protection**	**Owner**
A6.3.1/02	XXXX	1986	Iodopropynylbutyl carbamate (IPBC) 4 week dieatry dose range finding study in rats Source: XXXX Report No.: XX 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
A6.3.1/04	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	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	XXXX	1994	Omacide IPBC - 2-week repeat dose inhalation toxicity study in rats Source XXXX Report No.: XX 6/932373 GLP; (unpublished) Doc. No.: 531-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A6.3.3/02	XXXX	1994	Omacide IPBC - 5-day repeat dose inhalation toxicity study in rats Source: XXXX Report No.: XX 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	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.)	SOSTRAM Corporation
A6.4.1/02	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	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	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	XXXX	1994	Omacide IPBC - 13-week inhalation toxicity study in rats Source: XXXX Report No.: XX 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

Doc IIA **Section No./ Reference No.**	**Author(s)**	**Year**	**Title** **Source (laboratory)** **Report No.** **GLP; (un)published** **Doc. No.**	**Data protection**	**Owner**
A6.6.1/01	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	XXXX	2001	Preventol MP 100 - In vitro chromosome aberration test with chinese hamster V79 cells Source: XXXX Report No.: XX 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	XXXX	2001	Preventol MP 100 - V79/HPRT-Test in vitro for the detection of induced forward mutations Source: XXXX Report No.: XX 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	XXXX	1993	Omacide IPBC - Micronucleus cytogenetic assay in mice Source: XXXX Report No.: TC727.122 GLP; (unpublished) Doc. No.: 557-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A6.6.4	XXXX	1984	In vivo micronucleus assay in mice 3-iodo-2-propynyl butyl carbamate (IPBC) Source: XXXX Report No. TC-0135 GLP; (unpublished) Doc. No. 557-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.7/01	XXXX	1989	3-iodo-2-propynyl butyl carbamate (IPBC) 104 week dietary carcinogenicity study in rats (Volume 1 and 2) Source: XXXX Report No.: TC-0411 435580 GLP; (unpublished) Doc. No.: 537-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.7/02	XXXX	1988	3-iodo-2-propynyl butyl carbamate (IPBC) chronic dietary toxicity study in rats Source: XXXX Report No.: 5261 XX 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	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	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	XXXX	1989	IPBC 78 week dietary carcinogenicity study in mice Volume 2 to 3 (803 pages) Source: XXXX Report No.: TC-0409 XX 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

Doc IIA **Section No./ Reference No.**	**Author(s)**	**Year**	**Title** **Source (laboratory)** **Report No.** **GLP; (un)published** **Doc. No.**	**Data protection**	**Owner**
A6.7/06	XXXX	1989	IPBC 78 week dietary carcinogenicity study in mice Volume 2 continued to 3 (803 pages) Source: XXXX Report No.: TC-0409 XX 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	XXXX	1989	IPBC 78 week dietary carcinogenicity study in mice Volume 3 to 3 (803 pages) Source: XXXX Report No.: TC-0409 XX 7304 GLP; (unpublished) Doc. No.: 555-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.7/08	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
A6.8.1/02	XXXX	1994	Omacide IPBC - Oral (Gavage) rabbit developmental toxicity study Source: XXXX Report No.: XXXX GLP; (unpublished) Doc. No.: 551-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A6.8.1/04	XXXX	1994	Omacide IPBC - Oral (Gavage) rat development toxicity (Teratogenicity) study Source: XXXX Report No.: XXXX GLP; (unpublished) Doc. No.: 551-008	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A6.8.2/01	XXXX	1996	Omacide IPBC - Oral (Gavage) rat one generation (expanded to two generation) reproductive toxicity study (3 Volumes) Source: XXXX Report No.: XXXX GLP; (unpublished) Doc. No.: 553-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A6.8.2/05	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	XXXX	2004	Historical control data of two/one generation oral (Dietary Administration) reproduction toxicity studies 1984 to 1990 Source: XXXX Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 553-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.9/01	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

Doc IIA **Section No./ Reference No.**	**Author(s)**	**Year**	**Title** **Source (laboratory)** **Report No.** **GLP; (un)published** **Doc. No.**	**Data protection**	**Owner**
A6.9/02	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	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	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
A6.9/06	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	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	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	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
A6.11/01	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	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

Doc IIA **Section No./ Reference No.**	**Author(s)**	**Year**	**Title** **Source (laboratory)** **Report No.** **GLP; (un)published** **Doc. No.**	**Data protection**	**Owner**
A6.12.1/02	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	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.
A6.12.6/01	Bryld, L.E. Agner, R. Rastogi, S.C.	1997	Iodopropynyl butylcarbamate: a new contact allergen Source: Contact Dermatitis vol. 36, pp. 156-158, 1997 Report No.: Not applicable Not GLP; (published) Doc. No.: 592-003	No	N.R.
A6.12.6/02	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	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	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	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	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.
A7.1.1.1.1/01	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	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

Doc IIA **Section No./ Reference No.**	**Author(s)**	**Year**	**Title** **Source (laboratory)** **Report No.** **GLP; (un)published** **Doc. No.**	**Data protection**	**Owner**
A7.1.1.1.2/01	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	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	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, ISP, LANXESS, SOSTRAM, TROY)
A7.1.1.2.1/01	Grützner, I.	2002	Ready biodegradability of IPBC in a manometric respirometry test Source: Research and Consulting Company, Itingen, Switzerland Report No.: TC-1261 831172 GLP; (unpublished) Doc. No.: 713-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A7.1.1.2.2/01	Seyfried, B.	N.I.	Interim Report - 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.: 713-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, LANXESS, SOSTRAM, TROY)
A7.1.1.2.2/01	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, LANXESS, SOSTRAM, TROY)
A7.1.2.2.2/01	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	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.)	SOSTRAM Corporation
A7.1.3/02	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	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

Doc IIA **Section No./ Reference No.**	**Author(s)**	**Year**	**Title** **Source (laboratory)** **Report No.** **GLP; (un)published** **Doc. No.**	**Data protection**	**Owner**
A7.2.3.1/01	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, ISP, LANXESS, SOSTRAM, TROY)
A7.3.1/01	Görg, J.	2004	Estimation of photochemical degradation of IPBC using the Atkinson calculation method - IPBC 3-Iodo-2-propynyl-butylcarbamate Source: Scientific Consulting Company, Wendelsheim, Germany Report No.: 824-006 Not GLP; (unpublished) Doc. No.: 743-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, ISP, LANXESS, SOSTRAM, TROY)
A7.4.1.1/01	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	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	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	XXXX	2001	Preventol MP 100 - Acute Fish Toxicity Source: XXXX Report No.: 1025 XX 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	XXXX	1994	Acute toxicity of Omacide IPBC to the rainbow trout, Oncorhynchus mykiss Source: XXXX Report No.: 294- XXXX GLP; (unpublished) Doc. No.: 821-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A7.4.1.1/05b	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	XXXX	1992	(Propargyl Butyl Carbamate) - Acute Toxicity to rainbow trout (Oncorhynchus mykiss) under flow-through condition Source XXXX Report No.: TC-0305 XX 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

Doc IIA **Section No./ Reference No.**	**Author(s)**	**Year**	**Title** **Source (laboratory)** **Report No.** **GLP; (un)published** **Doc. No.**	**Data protection**	**Owner**
A7.4.1.2/01	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	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	Peither, A.	2001	Toxicity of Polyphase P-100 to Scenedesmus subspicatus in a 72-hour algal growth inhibition test – (Included the Analytical Report – Determination of the Concentrations of the test item in test medium) Source: Research and Consulting Company, Itingen, Switzerland Report No.: 790413 790424 TC0072 GLP; (unpublished) Doc. No.: 823-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A7.4.1.3/02	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	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	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	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	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	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

Doc IIA **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	Reis, K.-H.	2004	Interim Report - 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.: 841-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, LANXESS, SOSTRAM, TROY)
A7.5.1.1/01	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, LANXESS, SOSTRAM, TROY)
A7.5.1.2/01	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, LANXESS, SOSTRAM, TROY)
A7.5.1.3/01	Spatz, B.	2004	!! DRAFT !! - 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.: 851-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, LANXESS, SOSTRAM, TROY)
A7.5.1.3/01	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, LANXESS, SOSTRAM, TROY)

The following documents are cited in Doc IIA only.

Chapter No./ Reference No	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A3/01 (Doc II A)	Shaw, D.	2004	To whom it may concern - Particle size of technical IPBC Source: Troy Corporation, USA Study No.: Not applicable Not GLP; (unpublished) Doc. No. 593-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A3/02 (Doc II A)	Semmler, H. Heilen, W.	2001	Elimination and prevention of microfoam Source: Not relevant; Study No.: Not applicable Not GLP; (published) Doc. No. 592-015	No	N.R.

Doc IIB **Section No./ Reference No.**	**Author(s)**	**Year**	**Title** **Source (laboratory)** **Report No.** **GLP; (un)published** **Doc. No.**	**Data protection**	**Owner**
B3.1/01 (sb)	Anonymous	2002	Safety data sheet - ALKYDAL F 681 TBA; Bayer AG, Leverkusen, Germany; Study No.: 023918/08 Not GLP; (unpublished) Doc. No. 955-002	No	N.R.
B3.1/01 (wb)	Anonymous	2000	Safety data sheet on Dowanol PNB glycol ether; Dow AgroSciences; Study No.: Not indicated Not GLP; (unpublished) Doc. No. 955-010	No	N.R.
B3.1/02 (sb)	Anonymous	2002	Data sheet - Hexylene Glycol; shell Forschung GmbH Ingelheim, Germany Study No.: S1218 Not GLP; (unpublished) Doc. No. 955-004	No	N.R.
B3.1/02 (wb)	Anonymous	2003	Safety data sheet in accordance with 91/155/EEC RESYDROL AY 586w/38WA; Surface Specialties Austria GmbH Study No.: Not indicated Not GLP; (unpublished) Doc. No. 955-013	No	N.R.
B3.1/03 (sb) B9/01 (sb)	Anonymous	2003	Data Sheet - Shellsol D60 IS 2.4.2, 7th Edition - Product Code Q3522; Shell Agrar, Ingelheim, Germany Study No.: Not applicable Not GLP; (unpublished); Doc. No. 955-018	No	N.R.
B3.1/03 (wb)	Anonymous	2002	Safety Data Sheet - Ammonia solution 25% Suprapur; E. Merck, Darmstadt, Germany; Study No.: Not indicated Not GLP; (unpublished) Doc. No. 955-014	No	N.R.
B3.1/04 (wb)	Palm, A.-L. Sterky, K.	2002	Safety Data Sheet - Berol 191; AKZO NOBEL; Study No.: Not indicated; Not GLP; (unpublished); Doc. No. 955-015	No	N.R.
A6.2/02	XXXX	1995	The in vitro percutaneous absorption through human abdominal epidermis of [14C]-IPBC (3-Iodo-2-Propynyl-N-Butyl-Carbamate) Source: XXXX Study No.: 155046 12367 TC0510 GLP; (unpublished) Doc. No. 511-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.4.1/01	XXXX	2002	Repeated dose toxicity 90-day oral toxicity study in rats with IPBC technical (Protram TM 98) Source: XXXX Study 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.)	SOSTRAM Corporation
A6.4.1/02	XXXX	1984	90-Day subchronic oral toxicity test in rats Source: XXXX Study 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
A6.4.2/01	XXXX	1991	91-day dermal toxicity study in rats with TROYSAN Polyphase P-100 Source: XXXX; Study 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
B6.5/01 (sb)	Larsen, P.B.	1996	Lit-search on white spirit - Component of solvent based IPBC model formulation Source: Not relevant Study No.: Not relevant Not GLP; (published) Doc. No. 091-003	No	N.R.

Doc IIB **Section No./ Reference No.**	**Author(s)**	**Year**	**Title** **Source (laboratory)** **Report No.** **GLP; (un)published** **Doc. No.**	**Data protection**	**Owner**
B6.5/02 (sb)	Anonymous	1982	Environmental health criteria 20 - Selected petroleum products; Not relevant; Study No.: Not relevant Not GLP; (published) Doc. No. 091-004	No	IPBC Task Force (ARCH, LANXESS, SOSTRAM, TROY)
A6.7/01	XXXX	1989	3-iodo-2-propynyl butyl carbamate (IPBC) 104 week dietary carcinogenicity study in rats (Volume 1 and 2) Source: XXXX Report No.: TC-0411 435580 GLP; (unpublished) Doc. No.: 537-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.8.2/01	XXXX	1996	Omacide (IPBC) - Oral (Gavage) rat one generation (expanded to two generation) reproductive toxicity study (3 Volumes) Source: XXXX Study No.: XXXX GLP; (unpublished) Doc. No. 553-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A6.8.2/05	XXXX	1987	Troysan Polyphase two generation oral (dietary administration) reproduction toxicity study in the rat (one litter per generation) Source: XXXX Study 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
B7.1.3/04	Morsing, M. Morsing, E. Bernth, N. Pedersen, E.	2006	Estimation of emissions of 3-iodo-2propynyl-butyl-carbamate (IPBC) from preservative treated wood in a laboratory test according to OECD guideline Source: Danish Technological Institute Study No.: 1006657-02-24 Not GLP; (unpublished) Doc. No. 732-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, ISP, LANXESS, SOSTRAM, TROY)
B8.2/02	XXXX	1999	Measurements and assessment of dermal and inhalation exposure to Didecyldimethylammonium chloride (DDAC) used in the protection of cut lumber Source: XXXX Study No.: Not applicable Not GLP; (unpublished) Doc. No. 575-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation

The following documents are cited in Doc IIB only:

Chapter No./ Reference No	**Author(s)**	**Year**	**Title** **Source (laboratory)** **Report No.** **GLP; (un)published** **Doc. No.**	**Data protection**	**Owner**
B8/01 (Doc II B)	Anonymous	1900	Studies, Data, Models and Pattern of use defaults Source: Not relevant Study No.: Not applicable Not GLP; (unpublished) Doc. No. 575-001	No	IPBC Task Force (ARCH, LANXESS, SOSTRAM, TROY)

B8.2/01 (Doc IIB)	Lingk, W. Reifenstein, H. Westphal, D.	2005	Human exposure to wood preservatives Source: BfR Berlin and BMLFUW Vienna Not GLP; (unpublished) Doc. No. 575-002	No	N.R.
B8.2/03 (Doc IIB)	Müller, C. Hofer, M.	2006	98/8/EEC Review of IPBC - Statement related to the Relevance of Iodine Intake due to Exposure to IPBC Source: SCC GmbH, Wendelsheim, Germany Study Number: Not applicable Not GLP; (unpublished) Doc. No. 581-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, ISP, LANXESS, SOSTRAM, TROY)

Doc II C **Section No./** **Reference No.**	**Author(s)**	**Year**	**Title** **Source (laboratory)** **Report No.** **GLP; (un)published** **Doc. No.**	**Data protection**	**Owner**
A6.2/02	XXXX	1995	The in vitro percutaneous absorption through human abdominal epidermis of [14C]-IPBC (3-Iodo-2-Propynyl-N-Butyl-Carbamate) Source: XXXX Study No.: 155046 12367 TC0510 GLP; (unpublished) Doc. No. 511-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.4.1/01	XXXX	2002	Repeated dose toxicity 90-day oral toxicity study in rats with IPBC technical (Protram TM 98); Source: XXXX Study No.: 20-4-0132-01 GLP; (unpublished) Doc. No. 533-005	Y (Data on existing a.s. submitted for the first time for entry into Annex I.)	SOSTRAM Corporation
A6.7/01	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
B8.2/02	XXXX	1999	Measurements and assessment of dermal and inhalation exposure to Didecyldimethylammonium chloride (DDAC) used in the protection of cut lumber Source: XXXX Study No.: Not applicable Not GLP; (unpublished) Doc. No. 575-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation

The following document is cited in Doc IIC:

Chapter No./ Reference No	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
B8.2/01 (Doc IIB)	Lingk, W. Reifenstein, H. Westphal, D.	2005	Human exposure to wood preservatives Source: BfR Berlin and BMLFUW Vienna Not GLP; (unpublished) Doc. No. 575-002	No	N.R.

The following document is cited in Doc IIIA:

Doc IIIA Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection	Owner
A3.1.1/01	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	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	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	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.)	SOSTRAM Corporation
A3.1.3/01	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	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, SOSTRAM, TROY)
A3.2/01	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	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.)	SOSTRAM Corporation
A3.4/01	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	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

Doc IIIA **Section No./ Reference No.**	**Author(s)**	**Year**	**Title** **Source (laboratory)** **Report No.** **GLP; (un)published** **Doc. No.**	**Data protection**	**Owner**
A3.4/03	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	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	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.)	SOSTRAM Corporation
A3.5/02	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	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	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	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	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	Polson, G.	1997	Physical and chemical properties of 3-Iodo-2-Propynylbutylcarbamate (IPBC-100) Source: Olin Central analytical Laboratory, Cheshire Report No.: 18-94B07IPBC GLP; (unpublished) Doc. No.: 146-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A3.10/02	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.)	SOSTRAM Corporation

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A3.10/03	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	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, LANXESS, SOSTRAM, TROY)
A3.11/02	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, LANXESS, SOSTRAM, TROY)
A3.13/01	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	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, ISP, LANXESS, SOSTRAM, TROY)
A3.16	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, ISP, LANXESS, SOSTRAM TROY)
A4.1/01	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	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	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, SOSTRAM, TROY)

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A4.2c/01	Bruckhausen, P.	2004	Development and validation of the residue analytical method for the determination of IPBC and its 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, LANXESS, SOSTRAM, TROY)
A5.3.1/01	Briscoe, P.A. Williams, G.R. Anderson, D.G. Gadd, G.M.	1990	Microbial tolerance and biodetoxication of organic and organometallic biocides Source: IRG Secretariat Sweden Report No.: IRG/WP/1464 Not GLP; (published) Doc. No.: 392-011	No	N.R.
A5.3.1/02	Hansen, J.	1984	IPBC - A new fungicide for wood protection Source: IRG Secretariat Sweden Report No.: IRG/WP/3295 Not GLP; (published) Doc. No.: 392-002	No	N.R.
A6.1.1/01	XXXX	2000	Preventol MP 100 - Acute oral toxicity study in male and female wistar rats 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	XXXX	2000	Preventol MP 100 - Acute dermal toxicity study in male and female wistar rats XXXX Report No.: XX 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	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	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	XXXX	2000	Acute skin irritation test (patch test) of Preventol MP 100 in rabbits Source: XXXX Report No.: XX 7891 9300/450/95 XX 8069193 GLP; (unpublished) Doc. No.: 565-008	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	LANXESS Deutschland GmbH
A6.1.4/02	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.)	SOSTRAM Corporation
A6.1.5/01	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.)	SOSTRAM Corporation

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A6.1.5/02	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	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.: XX 30653 T5069983 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	XXXX	1995	Metabolism of 14C-IPBC in rats Source: XXXX Report No.: XX 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	XXXX	1995	The in vitro percutaneous absorption through human abdominal epidermis of [14C]-IPBC (3-Iodo-2-Propynyl-N-Butyl-Carbamate) Source: XXXX Report No.: 155046 12367 TC0510 GLP; (unpublished) Doc. No.: 511-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.3.1/01	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.: XX 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	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	XXXX	1986	Establishment of methodology and the routine analysis of Iodopropynylbutyl Carbamate in diets prepared for a 4 week dose range finding study (XX 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	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	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	XXXX	1994	Omacide IPBC - 2-week repeat dose inhalation toxicity study in rats Source: XXXX Report No.: XX 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

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A6.3.3/02	XXXX	1994	Omacide IPBC - 5-day repeat dose inhalation toxicity study in rats Source: XXXX Report No.: XX 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	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.)	SOSTRAM Corporation
A6.4.1/02	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	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	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	XXXX	1994	Omacide IPBC - 13-week inhalation toxicity study in rats Source: XXXX Report No.: XX 7/942772 GLP; (unpublished) Doc. No.: 535-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A6.4.3/02	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	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	XXXX	2001	Preventol MP 100 - In vitro chromosome aberration test with chinese hamster V79 cells Source: XXXX Report No.: XX 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	XXXX	2001	Preventol MP 100 - V79/HPRT-Test in vitro for the detection of induced forward mutations Source: XXXX Report No.: XX 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

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A6.6.4/01	XXXX	1993	Omacide IPBC - Micronucleus cytogenetic assay in mice Source: XXXX Report No.: TC727.122 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	XXXX	1989	3-iodo-2-propynyl butyl carbamate (IPBC) 104 week dietary carcinogenicity study in rats (Volume 1 and 2) Source: XXXX Report No.: TC-0411 435580 GLP; (unpublished) Doc. No.: 537-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.7/02	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	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	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	XXXX	1989	IPBC 78 week dietary carcinogenicity study in mice Volume 2 to 3 (803 pages) Source: XXXX Report No.: TC-0409 XX 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	XXXX	1989	IPBC 78 week dietary carcinogenicity study in mice Volume 2 continued to 3 (803 pages) Source: XXXX Report No.: TC-0409 XX 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	XXXX	1989	IPBC 78 week dietary carcinogenicity study in mice Volume 3 to 3 (803 pages) Source: XXXX Report No.: TC-0409 XX 7304 GLP; (unpublished) Doc. No.: 555-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.7/08	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	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

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A6.8.1/01	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	XXXX	1994	Omacide IPBC - Oral (Gavage) rabbit developmental toxicity study Source: XXXX Report No.: XX /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	XXXX	1994	Omacide IPBC - Oral (Gavage) rat development toxicity dose ranging study Source: XXXX Report No.: XX /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	XXXX	1994	Omacide IPBC - Oral (Gavage) rat development toxicity (Teratogenicity) study Source: XXXX Report No XX /19/R GLP; (unpublished) Doc. No.: 551-008	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A6.8.2/01	XXXX	1996	Omacide IPBC - Oral (Gavage) rat one generation (expanded to two generation) reproductive toxicity study (3 Volumes) Source: XXXX Report No.: XX 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	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	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	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	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

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A6.8.2/06	XXXX	2004	Historical control data of two/one generation oral (Dietary Administration) reproduction toxicity studies 1984 to 1990 Source: XXXX Report No.: Not indicated Not GLP; (unpublished) Doc. No.: 553-006	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A6.8.2/07	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	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	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	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	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	XXXX	2002	2-week dietary range-finding and palatability study with 3-iodopropynylbutyl carbamate (IPBC) in CD rats Source: XXXX Report No.: 7071-102 TC 1415 GLP; (unpublished) Doc. No.: 542-005	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation ARCH Chemicals
A6.9/06	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	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

Doc IIIA **Section No./ Reference No.**	**Author(s)**	**Year**	**Title** **Source (laboratory)** **Report No.** **GLP; (un)published** **Doc. No.**	**Data protection**	**Owner**
A6.9/08	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	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	XXXX	1996	Acute Neurotoxicity Validation Study with Paraoxon in Rats Source: XXXX Report No.: XX 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	XXXX	1996	Neurotoxicity Validation Study with Acrylamide in Rats Source: XXXX Report No.: XX 2100-030 Not GLP; (unpublished) Doc. No.: 541-008	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation ARCH Chemicals
A6.11/01	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	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	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	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	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	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.

Doc IIIA **Section No./ Reference No.**	**Author(s)**	**Year**	**Title** **Source (laboratory)** **Report No.** **GLP; (un)published** **Doc. No.**	**Data protection**	**Owner**
A6.12.6/02	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	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	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	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	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	Brasch, J. Schnuch, A. Geier, J. Aberer, W. Uter, W.	2004	Contact Dermatitis and Allergy Iodopropynylbutyl carbamate 0-2% is suggested for patch testing of patients with eczema possibly related to preservatives Source: British Journal of Dermatology 2004, Vol. 151, page 608-615, © 2004 British Association of Dermatologists Report No.: Not applicable Not GLP; (published) Doc. No.: 592-017	No	N.R.
A7.1.1.1.1/01	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	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	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.

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A7.1.1.1.2/02	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	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, ISP, LANXESS, SOSTRAM, TROY)
A7.1.1.2.1/01	Grützner, I.	2002	Ready biodegradability of IPBC in a manometric respirometry test Source: Research and Consulting Company, Itingen, Switzerland Report No.: TC-1261 831172 GLP; (unpublished) Doc. No.: 713-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A7.1.1.2.2/01	Seyfried, B.	N.I.	Interim Report - 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.: 713-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, LANXESS, SOSTRAM, TROY)
A7.1.1.2.2/01	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, LANXESS, SOSTRAM, TROY)
A7.1.2.2.2/01	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	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.)	SOSTRAM Corporation
A7.1.3/02	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	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	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, ISP, LANXESS, SOSTRAM, TROY)

Doc IIIA **Section No./ Reference No.**	**Author(s)**	**Year**	**Title** **Source (laboratory)** **Report No.** **GLP; (un)published** **Doc. No.**	**Data protection**	**Owner**
A7.3.1/01	Görg, J.	2004	Estimation of photochemical degradation of IPBC using the Atkinson calculation method - IPBC 3-Iodo-2-propynyl-butylcarbamate Source: Scientific Consulting Company, Wendelsheim, Germany Report No.: 824-006 Not GLP; (unpublished) Doc. No.: 743-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, ISP, LANXESS, SOSTRAM, TROY)
A7.4.1.1/01	XXXX	1994	Acute toxicity of Omacide IPBC to the fathead minnow (Pimephales promelas) Source: XXXX Report No.: 293- XX 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	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	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	XXXX	2001	Preventol MP 100 - Acute Fish Toxicity Source: XXXX Report No.: 1025 A/00 F 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	XXXX	1994	Acute toxicity of Omacide IPBC to the rainbow trout, Oncorhynchus mykiss Source XXXX Report No.: 294 XX GLP; (unpublished) Doc. No.: 821-004	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	ARCH Chemicals
A7.4.1.1/05b	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	XXXX	1992	(Propargyl Butyl Carbamate) - Acute Toxicity to rainbow trout (Oncorhynchus mykiss) under flow-through condition Source: XXXX Report No.: TC-0305 SLI 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	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

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A7.4.1.2/02	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	Peither, A.	2001	Toxicity of Polyphase P-100 to Scenedesmus subspicatus in a 72-hour algal growth inhibition test – (Included the Analytical Report – Determination of the Concentrations of the test item in test medium) Source: Research and Consulting Company, Itingen, Switzerland Report No.: 790413 790424 TC0072 GLP; (unpublished) Doc. No.: 823-003	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A7.4.1.3/02	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	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	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	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	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	Ward, G.S.	1991	TROYSAN Polyphase P-100 – Chronic toxicity to the water flea, Daphnia magna, under flow-through test conditions Source: Toxicon Environmental Sciences Report No.: TC-0294 J9009031b GLP; (unpublished) Doc. No.: 827-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	TROY Corporation
A7.5.1.1/01	Reis, K.-H.	2004	Interim Report - 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.: 841-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, LANXESS, SOSTRAM, TROY)

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A7.5.1.1/01	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, LANXESS, SOSTRAM, TROY)
A7.5.1.2/01	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, LANXESS, SOSTRAM, TROY)
A7.5.1.3/01	Spatz, B.	2004	!! DRAFT !! - 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.: 851-001	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, LANXESS, SOSTRAM, TROY)
A7.5.1.3/01	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, LANXESS, SOSTRAM, TROY)

The following document is cited in Doc IIIB:

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B3.1/01 (sb)	Anonymous	2002	Safety data sheet - ALKYDAL F 681 TBA; Bayer AG, Leverkusen, Germany; Study No.: 023918/08; Not GLP; (unpublished); Doc. No. 955-002	No	N.R.
B3.1/02 (sb)	Anonymous	2002	Data sheet - Hexylene Glycol; shell Forschung GmbH Ingelheim, Germany; Study No.: S1218; Not GLP; (unpublished); Doc. No. 955-004	No	N.R.
B3.1/03 (sb)	Anonymous	2003	Data Sheet - Shellsol D60 IS 2.4.2, 7th Edition - Product Code Q3522; Shell Agrar, Ingelheim, Germany; Study No.: Not applicable; Not GLP; (unpublished); Doc. No. 955-018	No	N.R.
B6.5/01 (sb)	Larsen, P.B.	1996	Lit-search on white spirit - Component of solvent based IPBC model formulation; Not relevant; Study No.: Not relevant; Not GLP; (published); Doc. No. 091-003	No	N.R.
B6.5/02 (sb)	Anonymous	1982	Environmental health criteria 20 - Selected petroleum products; Not relevant; Study No.: Not relevant; Not GLP; (published); Doc. No. 091-004	No	IPBC Task Force (ARCH, LANXESS, SOSTRAM, TROY)
B7.1.3/03	Wakeling, R.N. Cross, D.J. Eden, D.R. Maynard, P.N.	1994	Susceptibility of Antisapstain Fungicides to Rain Wash-Off; Not indicated; Study No.: IRG/WP/94-30046; Not GLP; (published); Doc. No. 792-001	No	N.R.
B7.1.3/04	Morsing, M. Morsing, E. Bernth, N. Pedersen, E.	2006	Estimation of emissions of 3-iodo-2propynyl-butyl-carbamate (IPBC) from preservative treated wood in a laboratory test according to OECD guideline; Danish Technological Institute; Study No.: 1006657-02-24; Not GLP; (unpublished); Doc. No. 732-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, ISP LANXESS, SOSTRAM, TROY)
B9/01 (sb)	Anonymous	2003	Data Sheet - Shellsol D60 IS 2.4.2, 7th Edition - Product Code Q3522; Shell Agrar, Ingelheim, Germany; Study No.: Not applicable; Not GLP; (unpublished); Doc. No. 955-018	No	N.R.

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IIIB (wb) **Section No./** **Reference No.**	**Author(s)**	**Year**	**Title** **Source (laboratory)** **Report No.** **GLP; (un)published** **Doc. No.**	**Data protection**	**Owner**
B3.1/01 (wb)	Anonymous	2000	Safety data sheet on Dowanol PNB glycol ether; Dow AgroSciences; Study No.: Not indicated; Not GLP; (unpublished); Doc. No. 955-010	No	N.R.
B3.1/02 (wb)	Anonymous	2003	Safety data sheet in accordance with 91/155/EEC RESYDROL AY 586w/38WA; Surface Specialties Austria GmbH; Study No.: Not indicated; Not GLP; (unpublished); Doc. No. 955-013	No	N.R.
B3.1/03 (wb)	Anonymous	2002	Safety Data Sheet - Ammonia solution 25% Suprapur; E. Merck, Darmstadt, Germany; Study No.: Not indicated; Not GLP; (unpublished); Doc. No. 955-014	No	N.R.
B3.1/04 (wb)	Palm, A.-L. Sterky, K.	2002	Safety Data Sheet - Berol 191; AKZO NOBEL; Study No.: Not indicated; Not GLP; (unpublished); Doc. No. 955-015	No	N.R.
B7.1.3/03	Wakeling, R.N. Cross, D.J. Eden, D.R. Maynard, P.N.	1994	Susceptibility of Antisapstain Fungicides to Rain Wash-Off; Not indicated; Study No.: IRG/WP/94-30046; Not GLP; (published); Doc. No. 792-001	No	N.R.
B7.1.3/04	Morsing, M. Morsing, E. Bernth, N. Pedersen, E.	2006	Estimation of emissions of 3-iodo-2propynyl-butyl-carbamate (IPBC) from preservative treated wood in a laboratory test according to OECD guideline; Danish Technological Institute; Study No.: 1006657-02-24; Not GLP; (unpublished); Doc. No. 732-002	Yes (Data on existing a.s. submitted for the first time for entry into Annex I.)	IPBC Task Force (ARCH, ISP, LANXESS, SOSTRAM, TROY)