Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

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

Product type: 13

ECHA/BPC/32/2014

Adopted

3 December 2014

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Opinion of the Biocidal Products Committee

on the application for approval of the active substance 3-iodo-2-propynyl butyl carbamate for product type 13

In accordance with Article 89(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 13 of the following active substance:

Common name:	**IBPC**
Chemical name(s):	**3-iodo-2-propynyl butyl carbamate**
EC No.:	**259-627-5**
CAS No.:	**55406-53-6**
Existing active substance	

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by the European Union IPBC Task Force (Arch Chemicals, Dow Benelux B.V., ISP Switzerland GmbH, Lanxess Deutschland GmbH, Troy Corp) on 31 July 2007, the evaluating Competent Authority Denmark submitted an assessment report and the conclusions of its evaluation to the Commission on 23 August 2013. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via the BPC and its Working Groups. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly.

Adoption of the BPC opinion

Rapporteur: BPC Member for Denmark.

The BPC opinion on the approval of the active substance 3-iodo-2-propynyl butyl carbamate (IPBC) in product type 13 was adopted on 3 December 2014.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the IPBC in product type 13 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of IPBC in product type 13. IPBC acts as a fungicidal active substance by reducing the numbers of viable fungi in metalworking fluids. IPBC has a carbamate structure and its target sites in fungi are cell membrane permeability and fatty acids. Specifications for the reference source are established.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product.

Validated analytical methods are available for the active substance as manufactured and for the relevant and significant impurities. Validated analytical methods are required and available for the relevant matrices. Methods were developed to analyse residues in soil, water, body fluids and tissues. Methods for the analysis of residues in air were not necessary because IPBC is not volatile and spray applications only involve non-respirable particles. An analytical method for the determination of residues of IPBC in/on food or feedstuffs is not required because the active substance is not used in a manner that may cause direct contact with food or feedstuffs.

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

The harmonised classification and labelling for IPBC according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Acute Tox 3 Acute Tox 4 Eye Dam. 1 Skin Sens. 1 STOT RE 1 Aquatic Acute 1 Aquatic Chronic 1
Labelling	
Pictograms	GHS05, GHS06, GHS08, GHS09
Signal Word	Danger
Hazard Statement Codes	H331: Toxic if inhaled H302: Harmful if swallowed H318: Causes serious eye damage

	H317: May cause an allergic skin reaction H372 (larynx): Causes damage to organs through prolonged or repeated exposure H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long-lasting effects
Specific Concentration limits, M-Factors	M = 10 for Aquatic Acute and 1 for Aquatic Chronic

b) Intended use, target species and effectiveness

The assessment of the biocidal activity of the active substance IPBC demonstrates that it has a sufficient level of efficacy against fungi and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that IPBC-based metalworking fluid preservative products may be expected to be efficacious. Biocidal products for metalworking fluid preservation have typical concentrations in the range of 10 to 40% IPBC. In end-use products (metalworking fluids), IPBC is contained at concentrations ranging from 0.005 to 0.1% w/w.

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

When the active substance is added to the concentrate to preserve the final emulsificable and water soluble metalworking fluid (MWF) solution, the dose of the biocide should be in accordance to the dilution instructions of the concerning metalworking fluid concentrate in order to reach an efficacious concentration in the final solution. The risk of resistance formation against carbamate fungicides is regarded to be low to medium by FRAC (Fungicide Resistance Action Committee). This applies to the use of carbamate fungicides in agriculture, where yearly applications to the same fields are possible. Based on the unspecific mode of action of IPBC, the risk of resistance formation caused by metalworking preservation is regarded to be low.

c) Overall conclusion of the evaluation including need for risk management measures

Human health

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

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

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios		
Scenario	**Primary or secondary exposure and description of scenario**	**Exposed group**
Mixing and loading(incidental hand contamination) (metalworking fluid dilution, sump maintenance)	Primary exposure (automated systems): In use concentration 0.2%-40% IPBC. Tier I: without PPE Tier II: with PPE (gloves)	Professionals
Metalworking	Primary exposure: In use concentration 0.005%-0.1% IPBC. Tier I: without PPE (100% clothing penetration) Tier II: with PPE (no gloves and coated coveralls)	Professionals
Tool setting and other tasks in the workshop (tool setting, dismantling the tool setting, handling work pieces)	Primary exposure: In use concentration 0.005%-0.1% IPBC. Tier 1: without PPE (100% clothing penetration) Tier II: PPE with coated coveralls Tier II: PPE with gloves and coated coveralls	Professionals
Combined exposure during the use of MWF (mixing and loading, metalworking and tool setting and other tasks)	Tier I: No PPE Tier II: PPE with coated coveralls Tier II: PPE with gloves and coated coveralls (no gloves during metalworking)	Professionals

Local effects:

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

Due to skin sensitizing property suitable PPE (gloves, coveralls) is required in the industrial use of the biocidal product at IPBC concentration of equal to or greater than 1%.

The risk for local respiratory effects was assessed qualitatively due to IPBC classification with STOT RE1; H372 (larynx) according to CLP (DSD T; R48/23).
Only professionals in automated processes are handling products classified with STOT RE1; H372 (larynx). These products (10-40 %IPBC) are either directly mixed into the MWFs or automatically diluted to a pre-solution of 0.2 to 4 % IPBC.

For all other uses for professionals the handling of the end products, which contains 0.005-0.1% IPBC, will not lead to classification of the end products for the larynx effect. During metal working aerosols might be generated when the MWF is in contact with fast rotating tools. However the STOT RE1 classification based on the larynx effects is not relevant since MWF (end product) will be below the classification limit for this effect. MWF contains 0.005-0.1% IPBC.

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

Systemic effects:

Exposure of professionals to IPBC was evaluated for the scenarios summarised in the table above.
The mixing and loading of the IPBC formulations to the metalworking fluids (MWF) and the use of MWF take place in industry. The uses of MWF are fully automated. In this industrial application large containers are used. During the mixing and loading phase, delivered containers are not handled manually due to their large size. Hand contamination by incidental exposure is considered using mixing and loading model 7 "Pouring liquid into systems" because the tasks described in this model most accurately apply to the above procedures.

Before the metals are further used by professionals or in industry, the processed metals are cleaned (e.g. with solvents). Therefore, it can be assumed that no residual MWF remains on the worked metals and thus, secondary exposure can be excluded.

The mixing and loading, application and post-application tasks could potentially occur on the same day. Therefore combined exposure was considered for all tasks.

Based on the overall risk characterization for professional users, safe uses were not identified when no Personal Protective Equipments (PPEs) are worn. As a consequence, the risk assessment was refined considering the use of the proper PPEs.

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

The combined exposure during mixing and loading, metalworking and tool setting during the use of MWF leads to unacceptable risks under worst case assumptions when no

gloves are worn. However, when gloves and coated coveralls are worn for all tasks other than metalworking, the combined exposure scenario shows that the risks are acceptable. Based on the above, safe uses were demonstrated when appropiate PPEs are worn.

Environment

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios	
Scenario	**Description of scenario including environmental compartments**
Preservatives for both emulsifiable and water soluble metal working fluids	According to the Emission Scenario Document (ESD) relevant emissions only take place during the life cycle stage waste treatment to the wastewater and not during industrial use. Emission to wastewater for a waste treatment facility receiving spent metal-working fluids and subsequent release to a sewage treatment plant (STP), surface water, sediment, soil and groundwater.

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

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

The Tier I assessment was performed by using two different Fproc values, an Fproc value of 0.2 (Tier Ia) and in addition an Fproc value of 0.05 (Tier Ib). In Tier II a dilution factor of 100 from the metalworking industry to the STP, a dilution factor of 100 from the STP into the river and a Fform value of 0.5 were considered as it was realised that the default suggested in the original ESD seems to be unrealistic.

IPBC degrades totally within 4 hours in a STP and IPBC will therefore not be present in the effluent. IPBC quickly degrades to PBC, iodide and iodate within the environmental compartments, and therefore PEC calculations of PBC, iodide and iodate have been performed for the environmental compartments, but not for IBPC.

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

The use of IPBC as metalworking fluid preservative results in direct emissions to a STP. The requirements for acceptable risk are met for Tier Ia and Tier II; however a risk is identified for Tier Ib for both the STP and for surface water. A risk in the Tier I scenario is accepted as this scenario seems to be too conservative and is assumed to be unrealistic. The risk to the sediment is the same as that described for surface water. Therefore the risk of the sediment will not be considered further. The requirements for acceptable risk according to the TGD on Risk Assessment are met for Tier Ia and Tier II.

For surface water the predicted concentrations of both iodide and iodate are within the background level for the Tier II assessment. For Tier Ia the concentrations are only slightly above the background level. For soil, predicted concentrations for all scenarios are well within the background level which is found acceptable.

By using the FOCUS model PEARL it could be shown that IPBC and PBC do not leach to groundwater from the soil surface, thus posing no risk to the groundwater compartment. The groundwater assessment for iodide and iodate calculated according to the "TGD on Risk Assessment" show that iodide and iodate do not pose a risk to the groundwater for the Tier Ia and Tier II assessment.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		Conclusions
CMR properties	Carcinogenicity (C)	Not classified
	Mutagenicity (M)	Not classified
	Toxic for reproduction (R)	Not classified
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	not P and not vP
	Bioaccumulative (B) or very Bioaccumulative (vB)	not B and not vB
	Toxic (T)	T
Endocrine disrupting properties	Active substance is not considered to have endocrine disrupting properties	

Consequently, the following is concluded:

IPBC does not meet the exclusion criteria laid down in Article 5 of Regulation (EU) No 528/2012.

IPBC does not meet the conditions laid down in Article 10 of Regulation (EU) No 528/2012, and is therefore not considered as a candidate for substitution. The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking

decisions on the approval of active substances under the BPR"[1] and in line with "Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR"[2] agreed at the 54th and 58th meeting, respectively of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

2.2.2. POP criteria

IPBC and PBC do not fulfil the criteria for a substance being a persistent organic pollutant (POP)

2.3. BPC opinion on the application for approval of the active substance IPBC in product type 13

In view of the conclusions of the evaluation, it is proposed that IPBC shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: minimum purity of the active substance evaluated: minimum purity 980 g/kg.

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

3. For industrial or professional users, safe operational procedures and appropriate organizational measures shall be established. Only where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.

4. Loading of the products into metal working fluids shall be semi-automated or automated, unless it can be demonstrated at product authorization that risks to professional users can be reduced to an acceptable level by other means.

5. The active substance does not fulfil the critea according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) 528/2012 due to its classification as acutely toxic in category 3, being a skin sensitiser and classified as a specific target organ toxicant by repeated exposure.

[1] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc)

[2] See document: Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc)

2.4. Elements to be taken into account when authorising products

1. Whilst the efficacy data provided is sufficient to recommend approval of the substance, data demonstrating the efficacy of the product at the minimum application rate against the range of proposed target organisms using the recommended application equipment must be provided at the product authorisation stage. Simulated use studies are required on the efficacy of the test substance over longer periods of time and on the effects of interfering substances in the products to be preserved.

2. The environmental exposure assessment for PT 13 as described in the Emission Scenario Document (ESD) is being revised currently. The exposure for IPBC was estimated based on an intermediate revision of the ESD agreed at the Environment Working Group, which is described in the assessment report. At product authorisation, if available, the revised ESD has to be considered. The revised ESD may also contain on-site treatment of waste which was not considered in the current evaluation. If at product authorisation the revised ESD is not available, values for Fproc for the specific process in which MWFs are used need to be specified.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of IPBC.

The applicants used "dummy" products as part of their submission. Further data may be required, in particular regarding the physical and chemical properties, efficacy and dermal absorption of the products and should be provided by applicants at the product authorization stage.

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