

**HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN  
BIOCIDEN**

**BIJLAGE II** bij het besluit d.d. 6 oktober 2017 tot toelating van de biocidefamilie Fungitrol Biocidal Product Family, toelatingnummer NL-0016703-0000

# **Evaluation Report Mutual Recognition**

## **Fungitrol Biocidal Product Family**

6 October 2017

Biocidal product assessment report related to product  
authorisation under (EU) Regulation 528/2012

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# 1 General information about the product application

<b>Name and address of the authorisation holder</b>	<b>Name</b>	TROY CHEMICAL COMPANY BV
	<b>Address</b>	Uiverlaan 12E 3145XN Maassluis The Netherlands
<b>Authorisation number</b>	NL-0016703-0000	
<b>Date of the authorisation</b>	6 October 2017	
<b>Expiry date of the authorisation</b>	27 July 2027	

<b>Trade name(s)</b>	Fungitrol Biocidal Product Family
Evaluating member state	Denmark
Name of the product in RMS	Fungitrol Biocidal Product Family
Active substance	3-iodo-2-propynylbutylcarbamate (IPBC)
PT	6
User category	Industrial

## 2 Summary of the product assessment

### 2.1 Classification and labelling

#### Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

MetaSPC1: Fungitrol P100 (100% w/w):

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The identity of all substances in the mixture that contribute to the classification of the mixture *:			
IPBC			
Pictogram:	GHS05 GHS06 GHS08 GHS09	Signal word:	danger
H-statements:	H302 H317 H318 H331 H372 H410	Harmful if swallowed. May cause an allergic skin reaction. Causes serious eye damage. Toxic if inhaled. Causes damage to larynx through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects.	
P-statements:	P260	Do not breathe	

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		dust/fume/gas/mist/vapours/spray.
	P270	Do not eat, drink or smoke when using this product.
	P272	Contaminated work clothing should not be allowed out of the workplace.
	P273	Avoid release to the environment.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor/... if you feel unwell.
	P302+P352	IF ON SKIN: Wash with plenty of water/...
	P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
	P305+P351+P338+P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor/....
	P403+P233	Store in a well-ventilated place. Keep container tightly closed.
	P391	Collect spillage.
	P405	Store locked up.
	P501	Dispose of contents/container to ....
Supplemental Hazard information:	-	

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MetaSPC2: Fungitrol 400G (100% w/w):

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The identity of all substances in the mixture that contribute to the classification of the mixture:

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IPBC

Pictogram:	GHS05 GHS06 GHS08 GHS09	Signal word:	danger
H-statements:	H302 H317 H318 H331 H372  H410	Harmful if swallowed. May cause an allergic skin reaction. Causes serious eye damage. Toxic if inhaled. Causes damage to larynx through prolonged or repeated exposure.  Very toxic to aquatic life with long lasting effects.	
P-statements:	P260 P270 P272 P273 P280  P301+P312  P302+P352 P304+P340	Do not breathe dust/fume/gas/mist/vapours/spray. Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection. IF SWALLOWED: Call a POISON CENTER/doctor/... if you feel unwell. IF ON SKIN: Wash with plenty of water/... IF INHALED: Remove person to fresh air and keep comfortable for breathing.	

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	P305+P351+P338+P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor/....
	P403+P233	Store in a well-ventilated place. Keep container tightly closed.
	P391	Collect spillage.
	P405	Store locked up.
	P501	Dispose of contents/container to ....
Supplemental Hazard information:	-	

MetaSPC3: Polyphase 720 (20% w/w):

The identity of all substances in the mixture that contribute to the classification of the mixture:		
IPBC		
Pictogram:	GHS05 GHS07 GHS08 GHS09	Signal word: danger
H-statements:	H317 H318 H332 H372  H410	May cause an allergic skin reaction. Causes serious eye damage. Harmful if inhaled. Causes damage to larynx through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects.
P-statements:	P260 P270 P272 P273 P280  P302+P352 P304+P340  P305+P351+P338+P310  P391 P501	Do not breathe dust/fume/gas/mist/vapours/spray. Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN: Wash with plenty of water/... IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor/.... Collect spillage. Dispose of contents/container to ....
Supplemental Hazard information:	-	

MetaSPC4: Polyphase L30 DPG (30% w/w):

The identity of all substances in the mixture that contribute to the classification of the mixture:		
IPBC		
Pictogram:	GHS05 GHS07	Signal word: danger

	GHS08	
	GHS09	
H-statements:	H302	Harmful if swallowed.
	H317	May cause an allergic skin reaction.
	H318	Causes serious eye damage.
	H332	Harmful if inhaled.
	H372	Causes damage to larynx through prolonged or repeated exposure.
	H410	Very toxic to aquatic life with long lasting effects.
P-statements:	P260	Do not breathe dust/fume/gas/mist/vapours/spray.
	P270	Do not eat, drink or smoke when using this product.
	P272	Contaminated work clothing should not be allowed out of the workplace.
	P273	Avoid release to the environment.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor/... if you feel unwell.
	P302+P352	IF ON SKIN: Wash with plenty of water/...
	P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
	P305+P351+P338+P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor/....
	P391	Collect spillage.
	P501	Dispose of contents/container to ....
Supplemental Hazard information:	-	

## 2.2 Packaging and shelf-life

### Professional

	Packaging authorised/ evaluated by RMS	Packaging applied for in NL	Packaging authorised in NL
<b>Meta SPC 1 and 2</b>			
Packaging size and type	20-25kg cardboard box with inner LDPE plastic bag and tape closure	20-25kg cardboard box with inner LDPE plastic bag and tape closure	20-25kg cardboard box with inner LDPE plastic bag and tape closure
Packaging size and type	25-50kg fiber drum with inner LDPE plastic bag and steel cover with lever lock ring closure	25-50kg fiber drum with inner LDPE plastic bag and steel cover with lever lock ring closure	25-50kg fiber drum with inner LDPE plastic bag and steel cover with lever lock ring closure
<b>Meta SPC 3 and 4</b>			
Packaging size and type	20-30kg HDPE pail with HDPE screw cap closure	20-30kg HDPE pail with HDPE screw cap closure	20-30kg HDPE pail with HDPE screw cap closure
Packaging size and type	20-200kg HDPE drum with	20-200kg HDPE drum	20-200kg HDPE drum

type	HDPE screw cap closure	with HDPE screw cap closure	with HDPE screw cap closure
Packaging size and type	1000kg HDPE IBC with HDPE screw cap closure	1000kg HDPE IBC with HDPE screw cap closure	1000kg HDPE IBC with HDPE screw cap closure

The shelf life of the product is 24 months in LDPE and HDPE.

## 2.3 Physico/chemical properties and analytical methods

For the assessment of the physical and chemical properties, analytical methods and risk assessment regarding physical and chemical properties we refer to the Product Assessment Report of the original authorisation by RMS DK.

## 2.4 Effectiveness against target organisms

For the assessment of the effectiveness against target organisms we refer to the Product Assessment Report of the original authorisation by RMS DK. The conclusions of the RMS are acceptable.

### 2.4.1 Instructions for the use(s)

The applicant has provided a Dutch SPC. This has been adapted to our standards.

## 2.5 Risk assessment for human health

For the risk assessment for human health we refer to the Product Assessment Report of the original authorisation. The Product Assessment Report (PAR) was prepared by the RMS Denmark (DK).

The Fungitrol Biocidal Product Family consists of four family members: Fungitrol P100, Fungitrol 400G, Polyphase 720 and Polyphase L30 DPG. Fungitrol P100 contains the active substance 3-Iodo-2-propynyl butyl carbamate (hereafter referred to as IPBC) at the concentration of 100% in powder form (w/w). Fungitrol 400G contains the active substance IPBC at the concentration of 100% in granular form (w/w). Polyphase 720, a ready-to-use liquid, contains the active substance IPBC at the concentration of 20% (w/w). Another ready-to-use liquid Polyphase L30 DPG contains the active substance IPBC at the concentration of 30% (w/w). The products are intended to be used for in-can preservation (PT6):

1. washing and cleaning fluids
2. paints and coatings
3. fluids used in textile production and leather emulsions
4. glues and adhesives
5. inks
6. mixtures to be used in concrete
7. pigment pastes

The Fungitrol products are added directly during the production process into the end-product (mixing and loading). The solid concentrates are diluted prior to obtain a pre-solution containing 5-30% IPBC that is mixed into the end product. Application rates in the end-product are in the range of: 0.005 (0.006 for pigment pastes) - 0.10% IPBC. The

biocidal product is used by professionals only. The preserved products could be used by industrial professionals, professionals and non-professionals indoor and outdoor.

The biocidal products have not been tested for acute toxicity, primary irritancy or potential skin sensitisation. Testing of the products is, however, not required, when the toxicity of the biocidal products can be assessed on the basis of the intrinsic properties and the concentration of its individual ingredients. The only component which triggers the classification and labelling of the product is the active substance IPBC.

No dermal penetration studies are available for the biocidal products Fungitrol P100, Fungitrol 400G, Polyphase 720 and Polyphase L30 DPG, pertaining to the biocidal product family. However, the dermal penetration of the active substance IPBC from the biocidal products can be derived from other formulations where the dermal penetration of IPBC through human skin has been investigated in vitro (PT6 IPBC CAR, 2013). Dermal penetration values of 30%, 10% and 1.6% had been derived for solvent-based formulations at the IPBC concentrations of 0.6 - 2.3%, 2.3 - 17% and 17 - < 100%. Further it was considered justified in the CAR to use the lowest dermal penetration figure of 1.6% as derived for a solvent-based liquid formulation containing about 17% IPBC also for solid formulations as it is, in general, well accepted that dermal penetration of an active substance in a solid formulation is distinctly lower than in a water-based formulation and even lower than in an organic solvent-based formulation.

Thus, a dermal penetration rate of 1.6% was used in the human health exposure assessment to assess the dermal penetration of the active substance IPBC from the products Fungitrol P100, Fungitrol 400G, Polyphase 720 and Polyphase L30 DPG. For the end-use products containing 0.10% IPBC a default value of 75% is used.

For industrial exposure, the mixing and loading of the product was considered by DK. The mixing and loading is considered for the powder/granules and for liquid formulations both automated and manually.

For each end product to be conserved the application is considered for the risk assessment

End-products	Application	Post-application
Paints and Coatings	Automated spraying M& of treated paints in spraying equipment Manual spraying (prof / non-prof) Manual brushing/rolling (prof / non-prof)	Handling sprayed product (paint have dried) Cleaning spraying equipment Cleaning of a brush
Emulsions in the leather production	Mixing and Loading	Handling wet treated leather
Glues and adhesives	Application of carpet glue (prof / non-prof)	
Admixture in concrete production	Covered by paints and coatings	
Addition of pigment pastes to color paints	Mostly automated M&L Covered by paints and coatings	
Application of inks	Mostly automated	



	M&L Covered by paints and coatings	
Use of preserved washing/cleaning fluids	Application of preserved detergent (prof / non-prof)	Handling wet treated laundry

Exposure calculations were performed using the proposed models in the various HEEG opinions and HeAd hoc recommendations. Even in combined exposure (M&L, application and post-application) the risks were acceptable for the protected industrial and professional users of the products. The combined exposure due to use of the end-products by unprotected non-professional users leads to 44% of the AEL for manual spraying and 9% for brushing of paints and 8% for the application of glues. The conclusion of DK to authorise the Fungitrol biocidal product family is supported by the Ctgb.

As the meta-SPCs are classified for local effects (H317, H318), a qualitative exposure and risk assessment for IPBC during mixing and loading tasks of Fungitrol P100, Fungitrol 400G, Polyphase 720 and Polyphase L30 DPG is performed in line with the Guidance on the BPR, Volume III Human Health – Assessment & Evaluation, Parts B+C (vers. 2.1, Feb. 2017). No unacceptable risks for local effects are identified in connection with the use by industrial users and all the uses are considered acceptable. This also takes into account the wearing of gloves.

Several indirect exposure routes were assessed:

- by contact with painted surfaces (wet and dry)
- by wearing clothing which were washed with preserved detergent
- via residues in food in contact with painted surfaces

No unacceptable risks are identified in connection with the use by the general public and all the uses are considered acceptable. This accepted by the Ctgb. However, for professional use of treated paint by manual spraying coveralls are needed for a safe use. Therefore the following RMM is included in the SPC:

End use products:

The person responsible for the placing on the market of treated articles shall ensure that the label of these treated articles provides the following information:

For application by manual spraying, the following must be stated: "Wear protective chemical resistant coated coveralls during manual spraying".

Furthermore, DK did not identify any substance of concern. This is accepted by the Ctgb.

Based on this risk assessment, it was concluded that no adverse health effects are expected for the protected (gloves, suitable protective clothing) industrial user after dermal and respiratory exposure to IPBC as a result of the application of a member of the Fungitrol Biocidal Product Family, when used in accordance to the SPC. No adverse health effects are expected for the protected (gloves, suitable protective clothing) professional user after dermal and respiratory exposure to IPBC when using an end product treated with Fungitrol Biocidal Product Family.

Furthermore, when used according to the SPC, no adverse health effects are expected for the non-professional user of an end product and the general public by indirect exposure to IPBC as a result of the preservation of the end-product with a member of the Fungitrol Biocidal Product Family.

## 2.6 Risk assessment for the environment

The Fungitrol Biocidal Product Family consists of four meta SPCs. All families concern in-can preservatives (PT06) based on the active substance 3-Iodo-2-propynyl butyl carbamate, hereafter referred to as IPBC. The concentration active substance in the products ranges from 200 to 1000 g/kg. No substances of concern have been identified. The products are meant to preserve the following products in-can to prevent deterioration by fungi (the efficacious concentration in the preserved products are given between parentheses):

- washing and cleaning fluids (0.05-0.5 g IPBC/kg product);
- paints and coatings (0.05-1.0 g IPBC/kg product);
- additives used in textile production and leather emulsions (0.05-0.5 g IPBC/kg product);
- glues and adhesives (0.05-1.0 g IPBC/kg product);
- inks (0.05-0.5 g IPBC/kg product);
- concrete additives (0.05-1.0 g IPBC/kg product);
- pigment pastes (0.06-1.0 g IPBC/kg product).

The products are added to the final formulation by professionals, but preserved products (e.g. washing fluids, glues and paints) may be used by non-professionals as well.

The RMS has made references to the CAR for all applications that have been assessed before. For applications not addressed in the CAR the RMS has assessed environmental risks according to new insights and scenarios that have recently become available. For details on the risk assessment for the environment we refer to the Product Assessment Report of the original authorisation by RMS DK.

Iodine concentrations resulting from degradation of IPBC may exceed the PNEC in various compartments, but are in the lower ranges of the natural background concentrations except for preservation of leather additives for which concentrations are predicted (24 µg/L) above human risk limits (15 µg/L). However, such preservatives are only released to soils via distribution of sewage sludge on land, an emission route that is highly unlikely in The Netherlands as sewage sludge is usually treated as hazardous waste. Therefore, the accompanied risks are considered acceptable.

Due to spillage of paints and coatings during applications, the concentrations IPBC and metabolite PBC may exceed the PNEC. Risks for soil and groundwater may be therefore expected. Therefore, the following risk mitigation measures (RMMs) were proposed:

- The ground must be covered during in-situ application of the treated articles (paints and coatings) and any spillage should be collected.

As this is a RMM to be enforced to a third-party user, it is legally not binding. Therefore, the paint's manufacturer needs to add this RMM to the paint's label.

Emission was not calculated for preservation of printing inks as harmonised scenarios are currently not available. The RMS has proposed the following RMM instead:

- Any solid/liquid waste from the de-inking process must be treated as special waste and handled according to local regulations.

NL is of the opinion that the suggested RMM does not prevent emission to the aquatic environment as IPBC remains in the aqueous phase during deinking as this active is hydrophilic and subsequently discharged to the sewer. Moreover, the RMM needs to be enforced to a third party for which the SPC is legally not binding. Nevertheless, NL has calculated a PEC:PNEC of <1.5 for surface water based on worst-case assumptions. The accompanied risks are therefore considered acceptable.

The Netherlands agree with the conclusions made by the RMS, the proposed RMMs, and the proposed hazard and precautionary statements.

**Overall conclusion for the aspect environment:** The conclusions in the risk assessment of the RMS are valid.

## **2.7 Measures to protect man, animals and the environment**

For the measures to protect animals and the environment we refer to Product Assessment Report of the original authorisation and the SPC of the CMS NL.

## **2.8 Substitution/exclusion criteria and comparative assessment**

Fungitrol Biocidal Product Family does not contain any active substances that are considered candidate for substitution.

## **3 Decision**

The authorisation of Fungitrol Biocidal Product Family, including the products Fungitrol P100, Fungitrol 400G, Polyphase 720 and Polyphase L30 DPG, is based on mutual recognition of the authorisation of RMS Denmark. For the evaluation we refer to the product assessment report which has been composed by the RMS conform the Common Principles.

It is concluded that the application of Fungitrol P100, Fungitrol 400G, Polyphase 720 and Polyphase L30 DPG according to the use instructions as stated in the SPC, will be effective and that there will be no harm for the health of humans and for the environment.