

Summary of product characteristics for a biocidal product

Product name: Fungitrol 400G

Product type(s): PT13 - Working or cutting fluid preservatives (Preservatives)

Authorisation number: 578-30

R4BP 3 asset reference number: DK-0016529-0004

Table Of Contents

Administrative information	1
1.1. Trade names of the product	1
1.2. Authorisation holder	1
1.3. Manufacturer(s) of the biocidal products	2
1.4. Manufacturer(s) of the active substance(s)	2
2. Product composition and formulation	3
2.1. Qualitative and quantitative information on the composition of the biocidal product	3
2.2. Type of formulation	3
3. Hazard and precautionary statements	3
4. Authorised use(s)	4
5. General directions for use	7
5.1. Instructions for use	7
5.2. Risk mitigation measures	7
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	8
5.4. Instructions for safe disposal of the product and its packaging	8
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage	8
6. Other information	8

Authorisation number

578-30 1-4

R4BP 3 asset reference number

DK-0016529-0004

Date of the authorisation

20/12/2018

Expiry date of the authorisation

20/12/2028

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer

Troy Chemical Company BV

Address of the manufacturer

Poortweg 4C 2612PA Delft Netherlands

Location of manufacturing sites

Westelijke Randweg 9 4791 RT Klundert Netherlands

Industriepark 23 56593 Horhausen Germany

Am Alten Galgen 14 56410 Montabaur Germany

Geschwister-Scholl-Straße 127 39218 Schönebeck/Elbe Germany

Mecklenburger Str. 229 23568 Lübeck Germany

Halchtersche Str. 33 38304 Wolfenbüttel Germany

Am Nordturm 5 46562 Voerde Germany

1.4. Manufacturer(s) of the active substance(s)

Active substance	39 - 3-iodo-2-propynylbutylcarbamate (IPBC)
Name of the manufacturer	Troy Corporation
Address of the manufacturer	8 Vreeland Road 07932 Florham Park, New Jersey United States
Location of manufacturing sites	One avenue L 07105 Newark, New Jersey United States

Active substance	39 - 3-iodo-2-propynylbutylcarbamate (IPBC)
Name of the manufacturer	Troy Chemical Company BV
Address of the manufacturer	Poortweg 4C 2612PA Delft Netherlands
Location of manufacturing sites	Industriepark 23 56593 Horhausen Germany

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
3-iodo-2-propynylbutylcarbamate (IPBC)		Active Substance	55406-53-6	259-627-5	100

2.2. Type of formulation

GR - Granule

3. Hazard and precautionary statements

Hazard statements	<p>Toxic if inhaled.</p> <p>Harmful if swallowed.</p> <p>Causes serious eye damage.</p>
--------------------------	---

Precautionary statements

May cause an allergic skin reaction.
Causes damage to organs Larynx through prolonged or repeated exposure inhalation.
Very toxic to aquatic life with long lasting effects.

Do not eat, drink or smoke when using this product.
Wear face protection.
Wear eye protection.
Wear protective gloves.
Wear protective clothing.
Do not breathe dust.
Avoid release to the environment.
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.
Collect spillage.
Store in a well-ventilated place.Keep container tightly closed.
Store locked up.
Dispose of contents to in accordance with local/regional/national/international regulation.

4. Authorised use(s)

4.1 Use description

Use 1 - 1.0 Metal Working Fluid

Product type

PT13 - Working or cutting fluid preservatives (Preservatives)

Where relevant, an exact description of the authorised use

Please see field of use description

Target organism(s) (including development stage)

Scientific name: Yeasts
Common name: Yeasts
Development stage: vegetative cells

Scientific name: Fungi
Common name: Mould fungi
Development stage: vegetative cells

Field(s) of use	<p>Indoor</p> <p>The products of the IPBC Biocidal Product Family PT13 are used for preservation of synthetic and mineral oil-based metal working fluids (MWFs) in PT13. Metal working fluid preservative for industrial and professional use. It is incorporated in the metal working fluid concentrate or added to the diluted metal working fluid in use.</p>
Application method(s)	<p>Method: Closed and open system Detailed description:</p> <p>Addition to MWF concentrates during manufacturing (preventive treatment): When treating metal working fluid concentrates, the manufacturer must ensure that instructions for dosing are supplied with the metal working fluid concentrate such that an efficacious concentration of the active substance is achieved in the metal working fluid (in use) and such that the concentration of IPBC does not deviate from the range of 0.005-0.015% in the metal working fluid (in use).</p> <p>Tank-side addition to a metal working fluid in use (curative treatment): 0.005-0.015% (equivalent to 0.005-0.015% IPBC).</p>
Application rate(s) and frequencies	<p>Application Rate: Tank-side addition: 0.005 - 0.015 % biocidal product in the diluted MWF (corresponding to 0.005 - 0.015 % IPBC in the diluted MWF), Preventive treatment: see detailed description above. Dilution (%): 0 Number and timing of application: Preventive use: 1 application at the time of metal working fluid concentrate manufacturing.</p> <p>Curative use: 1 additional tank side application to the metal working fluid in the use phase (in case of contamination).</p>
Category(ies) of users	<p>Industrial</p> <p>Professional</p>
Pack sizes and packaging material	<p>25 kg Fiber drum with inner polyethylene bag liner, steel cover with lever lock ring. For manual handling.</p> <p>25-50 kg Fibre drum with inner polyethylene bag liner, steel cover with lever lock ring. For Automatic mixing and loading.</p>

4.1.1 Use-specific instructions for use

The product is a solid organic fungicide with a broad spectrum of activity against fungal organisms most commonly found in aqueous metalworking fluid systems.

The product is a metal working fluid preservative for professional use. It is incorporated in the metal working fluid concentrate or added to the diluted metal working fluid in use.

Incorporation into metal working fluid concentrates: When treating metal working fluid concentrates, the manufacturer must ensure that instructions for dosing are supplied with the metal working fluid concentrate such that an efficacious concentration of the active substance is achieved in the metal working fluid (in use) and such that the concentration of IPBC does not deviate from the range of 0.005-0.015% in the metal working fluid (in use).

Addition to the diluted metal working fluid in use: The product should be diluted with dipropylene glycol in an automated process prior to addition to the storage tank of the metal working fluid in use.

It is recommended that the optimum biocide concentration and compatibility with individual formulations is determined by means of laboratory tests.

Read product label and directions for use before the product is used. Prevent direct contact with strongly acidic or alkaline chemicals.

The pH stability is between 3 and 10.5. As standard good practice it is advisable to check the compatibility in the final formulation.

4.1.2 Use-specific risk mitigation measures

Avoid contact with eyes, skin and clothing. Do not breathe dust. Avoid release to the environment.

Keep in the original container kept tightly closed when not in use.

Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed.

Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas.

During product handling phase:

Wear protective chemical resistant gloves (Material to be specified by the authorisation holder within the product information).

Wear coated coveralls (Material to be specified by the authorisation holder within the product information).

Wear eye protection, the use of eye protection is mandatory.

Wear appropriate respirator (material to be specified by authorization holder within the product information)

4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Avoid all unnecessary release to the environment; in particular avoid release to water.

Eye contact: Get medical attention immediately. Call a poison center or physician. Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes.

Chemical burns must be treated promptly by a physician.

Inhalation: Get medical attention immediately. Call a poison center or physician. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Skin contact: Get medical attention immediately. Call a poison center or physician. Wash with plenty of soap and water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Chemical burns must be treated promptly by a physician. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse. If symptoms persists, seek medical attention.

Ingestion: Get medical attention immediately. Call a poison center or physician. Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Chemical burns must be treated promptly by a physician. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Protection of first-aiders: No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Water polluting material. May be harmful to the environment if released in large quantities. Collect spillage.

Small spill: Move containers from spill area. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Place spilled material in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor. Wear gloves while cleaning.
Large spill: Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor. Wear gloves while cleaning.

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and nonrecyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

Packaging

The generation of waste should be avoided or minimized wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions: This material and its container must be disposed of in a safe way.

Care should be taken when handling emptied containers that have not been cleaned or rinsed out.

Empty containers or liners may retain some product residues.

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Store between the following temperatures: $>0 - 32^{\circ}\text{C}$

Store in accordance with local regulations.

Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10 of the Safety Data Sheet) and food and drink.

Store locked up.

Keep container tightly closed and sealed until ready for use.

Containers that have been opened must be carefully resealed and kept upright to prevent leakage.

Do not store in unlabeled containers.

Use appropriate containment to avoid environmental contamination.

Shelf-life: 2 years.

5. General directions for use

5.1. Instructions for use

Please refer to use-specific instructions for use

5.2. Risk mitigation measures

Please refer to use-specific risk mitigation measures

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Please refer to use-specific particulars of direct or indirect effects, first aid instructions and emergency measures to protect the environment.

5.4. Instructions for safe disposal of the product and its packaging

Please refer to use-specific instructions for safe disposal of the product and its packaging

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Please refer to use-specific condition of storage and shelf-life of product under normal condition of storage

6. Other information

Pictogram to support the H-phrases: GHS05, GHS06, GHS08, GHS09

III. Etiketten skal indeholde nedenstående oplysninger. Oplysninger i citationstegn skal angives ordret:

1) I hovedfeltet:

"Konserveringsmiddel til metalkærevæsker

Må kun anvendes forebyggende ved tilsætning til metalkærevæskekoncentrater og til behandling af metalkærevæsker i brug mod svampe og gær."

2) I advarselsfeltet:

"FARE

Farlig ved indtagelse.

Giftig ved indånding.

Kan forårsage allergisk hudreaktion.

Forårsager alvorlig øjenskade.

Forårsager organskader (Strubehoved) ved længerevarende eller gentagen eksponering ved indånding.

Meget giftig med langvarige virkninger for vandlevende organismer.

Indånd ikke tåge/damp.

Bær beskyttelseshandsker/beskyttelsestøj/øjenbeskyttelse/ansigtsbeskyttelse."

(Handske- og beskyttelsestøjsmateriale skal angives af godkendelsesindehaveren i produktdatabladet)

"

Undgå udledning til miljøet.

Udslip opsamles.

Opbevares på et godt ventileret sted. Hold beholderen tæt lukket.

Vask huden efter arbejdet.

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

Kun til professionel og industriel anvendelse.

Må kun anvendes forebyggende ved tilsætning til metalkærevæskekoncentrater og til behandling af metalkærevæsker i brug mod svampe og gær.

Må kun anvendes i doseringer på 0,005-0,015 % (w/w) ved behandling af metalkærevæsker i brug.

Må ikke anvendes mod andre skadevoldere og ikke i højere doseringer end de i brugsanvisningen nævnte.

Ved håndtering af produktet skal der anvendes øjenbeskyttelse.

Ved tilsætning til metalkærevæskekoncentrater skal producenten sikre, at der medfølger det behandlede metalkærevæskekoncentrat instruktioner for dosering, der sikrer en effektiv koncentration af aktivstoffet i metalkærevæsken under brug, men således at koncentrationen af IPBC i metalkærevæsken under brug ikke afviger fra intervallet 0,005-0,015 % (w/w)

IPBC.

Må ikke tømmes i kloak afløb.
Opbevares under lås og utilgængeligt for børn.
Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.
Emballagen må ikke genanvendes"

Farepiktogrammet GHS05, GHS06, GHS08 og GHS09.

Miljøstyrelsen henleder opmærksomheden på, at godkendelsesindehaver skal anføre oplysninger om førstehjælp, herunder:

VED INDÅNDING: Flyt personen til et sted med frisk luft og sørg for, at vejrtrækningen lettes.

VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Fjern eventuelle kontaktlinser, hvis dette kan gøres let. Fortsæt skylning. Ring omgående til en GIFTINFORMATION eller læge.

VED KONTAKT MED HUDEN: Vask med rigeligt vand.

3) I deklarationsfeltet:

a) Teksten "Konservingsmiddel til metalskærevæske, BPR-reg.nr. 578-30-4-x(3). Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)".

b) Oplysning om præparattype: "granulat" for dette produkt.

c) Indholdet af aktivstof i vægtprocent (% w/w) og g/L ved 20 °C.

d) Udløbsdatoen skal anføres. Denne dato må højst være 2 år efter produktionsdatoen.

Etikettens dato kan udformes som en henvisning til en produktionsdato andetsteds på emballagen.

e) Batchnummer eller – betegnelse skal anføres.

f) Pakningsstørrelse i kg.

g) Godkendelsesindehavers navn og adresse.

4) Brugsanvisningen:

Oplysninger om skadevoldere, anvendelsesområde og doseringer.

Følgende retningslinjer gælder i forhold til bortskaffelse.

Der skal mærkes med sikkerhedssætning P501:

"Indholdet/beholderen bortskaffes i overensstemmelse med kommunale regler for affaldshåndtering."

Derudover skal mærkningen ske efter retningslinjerne:

"Rester skal afleveres til den kommunale affaldsordning for farligt affald. Tomme beholdere kan bortskaffes med dagrenovationen."

(3): "x" skal erstattes med et tal som angivet i godkendelsesbrevets bilag 4.