

Summary of product characteristics for a biocidal product family

Family name: IPBC Biocidal Product Family PT13

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

Authorisation number: 578-30

R4BP 3 asset reference number: DK-0016529-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

IPBC Biocidal Product Family PT13

1.2. Product type(s)

PT13 - Working or cutting fluid preservatives (Preservatives)

1.3. Authorisation holder

Name and address of the authorisation holder

| | |
|---------|--------------------------------------|
| Name | TROY CHEMICAL COMPANY BV |
| Address | Poortweg 4C 2612PA Delft Netherlands |

Authorisation number

578-30

R4BP 3 asset reference number

DK-0016529-0000

Date of the authorisation

20/12/2018

Expiry date of the authorisation

20/12/2028

1.4. 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 |

1.5. 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 family composition and formulation

2.1. Qualitative and quantitative information on the composition of the family

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|--|------------|------------------|------------|-----------|-------------|
| 3-iodo-2-propynylbutylcarbamate (IPBC) | | Active Substance | 55406-53-6 | 259-627-5 | 9,9 - 100 |

2.2. Type(s) of formulation

AL - Any other liquid

GR - Granule

Part II.- Second information level - meta SPC(s)

1. Meta SPC administrative information

1.1. Meta SPC identifier

IPBC 10

1.2. Suffix to the authorisation number

1-1

1.3 Product type(s)

PT13 - Working or cutting fluid preservatives (Preservatives)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|--|------------|------------------|------------|-----------|-------------|
| 3-iodo-2-propynylbutylcarbamate (IPBC) | | Active Substance | 55406-53-6 | 259-627-5 | 9,9 - 9,9 |

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

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

Precautionary statements

Wear protective gloves.
 Wear protective clothing.
 Wear face protection.
 Wear eye protection.
 Do not breathe mist.
 Do not breathe vapours.
 IF ON SKIN:Wash with plenty of water.
 IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing.
 Get medical attention if you feel unwell.
 Avoid release to the environment.
 Collect spillage.
 Dispose of contents to in accordance with local/regional/national/international regulation.

4. Authorised use(s) of the meta SPC

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 | Indoor 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. |
| Application method(s) | Method: Closed and open systems Detailed description: 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). Tank-side addition to a metal working fluid in use (curative treatment): 0.05-0.15% (equivalent to 0.005-0.015% IPBC) (0.1-0.15% for mineral oil based MWFs (equivalent to 0.01-0.015% IPBC)). |
| Application rate(s) and frequencies | Application Rate: 0.05 - 0.15 % biocidal product in the 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. Curative use: 1 additional tank side application to the metal working fluid in the use phase (in case of contamination). |

| | |
|--|--|
| Category(ies) of users | Industrial Professional |
| Pack sizes and packaging material | 5-30 kg Pail, Plastic HDPE, Screw cap HDPE 200-230 kg Drum, Plastic HDPE, Screw cap HDPE 1000-1100 kg IBC, Plastic HDPE Screw cap HDPE |

4.1.1 Use-specific instructions for use

The product is a liquid organic fungicide preparation 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).

The metal working fluid concentrate must be diluted by the user with water before use.

Addition to the diluted metal working fluid in use: The product can be added to metal working fluids in use by adding it to the storage tank of the metal working fluid in use. It is recommended that the optimum biocide concentration and compatibility with individual formulations be 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 vapor or mist. 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: 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. Get medical attention.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. 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. Get medical attention following exposure or if feeling unwell. 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: Wash skin thoroughly with soap and water or use recognized skin cleanser. Remove contaminated clothing and shoes. Continue to rinse for at least 10 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Ingestion: 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. Get medical attention following exposure or if feeling unwell. 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. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

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: Stop leak if without risk. Move containers from spill area. Dilute with water and mop up or absorb with an inert dry material. Place contaminated water or absorbent material in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor. Wear gloves while cleaning.

Large spill: Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via a licensed waste disposal contractor. Wear gloves while cleaning. Contaminated absorbent material may pose the same hazard as the spilled product.

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

Waste treatment methods

Product: Dispose of in accordance with the European Directives on waste and hazardous waste. Do not contaminate ponds, waterways or ditches with chemical or used container. Container hazardous when empty. Dispose of in accordance with local regulations.

Contaminated packaging: Empty remaining contents. Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal.

Do not re-use empty containers.

Do not burn, or use a cutting torch on, the empty drum.

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: 5 – 35 °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 of the meta SPC

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: GHS07, 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:

"ADVARSEL

Forårsager hudirritation.

Kan forårsage allergisk hudreaktion.

Forårsager alvorlig øjenirritation.

Kan forårsage 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.

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 0,05-0,15 % (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 utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.

"

Farepiktogrammet GHS07, GHS08 og GHS09.

Miljøstyrelsen henleder opmærksomheden på, at godkendelsesindehaver skal anføre

oplysninger om førstehjælp, herunder:

VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Fjern eventuelle kontaktlinser, hvis dette kan gøres let. Fortsæt skylning.

VED KONTAKT MED HUDEN: Vask med rigeligt vand.

3) I deklarationsfeltet:

a) Teksten "Konserveringsmiddel til metalkærevæske, BPR-reg. nr. 578-30-1-x(3). Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)".

b) Oplysning om præparattype: "væske" 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.

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

| | |
|-----------------|-----------------|
| Troyshield PA10 | Market area: DK |
| Troyshield PA10 | Market area: AT |
| Troyshield PA10 | Market area: BE |
| Troyshield PA10 | Market area: BG |
| Troyshield PA10 | Market area: CZ |
| Troyshield PA10 | Market area: FI |
| Troyshield PA10 | Market area: FR |
| Troyshield PA10 | Market area: DE |
| Troyshield PA10 | Market area: HU |
| Troyshield PA10 | Market area: IT |
| Troyshield PA10 | Market area: LU |
| Troyshield PA10 | Market area: NL |
| Troyshield PA10 | Market area: NO |
| Troyshield PA10 | Market area: PL |
| Troyshield PA10 | Market area: PT |

| | |
|--|-----------------|
| Troyshield PA10 | Market area: RO |
| Troyshield PA10 | Market area: SK |
| Troyshield PA10 | Market area: SI |
| Troyshield PA10 | Market area: ES |
| Troyshield PA10 | Market area: SE |
| Troyshield PA10 | Market area: CH |
| Troyshield PA10 | Market area: GB |
| Authorisation number (R4BP 3 asset reference number - National Authorisation) DK-0016529-0001 1-1 | |

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|--|------------|------------------|------------|-----------|-------------|
| 3-iodo-2-propynylbutylcarbamate (IPBC) | | Active Substance | 55406-53-6 | 259-627-5 | 9,9 |

1. Meta SPC administrative information

1.1. Meta SPC identifier

IPBC 20

1.2. Suffix to the authorisation number

1-2

1.3 Product type(s)

PT13 - Working or cutting fluid preservatives (Preservatives)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|--|------------|------------------|------------|-----------|-------------|
| 3-iodo-2-propynylbutylcarbamate (IPBC) | | Active Substance | 55406-53-6 | 259-627-5 | 20 - 20 |

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Harmful if swallowed. Harmful if inhaled.
Causes serious eye damage.
Causes skin irritation.
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.

Precautionary statements

Wear protective gloves.
Wear protective clothing.

Wear eye protection.

Wear face protection.

Avoid release to the environment.

Do not breathe vapours.

Do not breathe mist.

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.

Dispose of contents to in accordance with local/regional/national/international regulation.

4. Authorised use(s) of the meta SPC

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) | <p>Scientific name: Yeasts Common name: Yeasts Development stage: vegetative cells</p> <p>Scientific name: Fungi Common name: Mould fungi Development stage: vegetative cells</p> |
| 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: 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</p> |

| | |
|---|---|
| | <p>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): 0.025-0.075% (equivalent to 0.005-0.015% IPBC).</p> |
| <p>Application rate(s) and frequencies</p> | <p>Application Rate: Tank-side addition: 0.025 - 0.075 % biocidal product in the diluted MWF (corresponding to 0.005 - 0.015 % IPBC in the diluted MWF). Preventive treatment: please see detailed description 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> |
| <p>Category(ies) of users</p> | <p>Industrial Professional</p> |
| <p>Pack sizes and packaging material</p> | <p>5-30 kg Pail, Plastic HDPE, Screw cap HDPE</p> <p>200-230 kg Drum, Plastic HDPE Screw cap HDPE</p> <p>1000-1100 kg IBC, Plastic HDPE, Screw cap HDPE</p> |

4.1.1 Use-specific instructions for use

The product is a liquid organic fungicide preparation 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).

The metal working fluid concentrate must be diluted by the user with water before use.

Addition to the diluted metal working fluid in use: The product can be added to metal working fluids in use by adding it to the storage tank of the metal working fluid in use. It is recommended that the optimum biocide concentration and compatibility with individual formulations be 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 vapor or mist. 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. Flush contaminated skin with plenty of 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. Wash clothing before reuse.

Clean shoes thoroughly before reuse.

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: Stop leak if without risk. Move containers from spill area. Dilute with water and mop up or absorb with an inert dry material. Place contaminated water or absorbant material in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor. Wear gloves while cleaning.

Large spill: Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Wear gloves while cleaning.

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

Waste treatment methods.

Product: Dispose of in accordance with the European Directives on waste and hazardous waste. Do not contaminate ponds, waterways or ditches with chemical or used container. Container hazardous when empty. Dispose of in accordance with local regulations.

Contaminated packaging: Empty remaining contents. Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal.

Do not re-use empty containers.

Do not burn, or use a cutting torch on, the empty drum.

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: 5 – 35 °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 of the meta SPC

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, GHS07, 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.
Farlig ved indånding.
Forårsager hudirritation.
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.
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 0,025-0,075 % (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 utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.

Emballagen må ikke genanvendes.

"

Farepiktogrammet GHS05, GHS07, 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 vejtrækningen 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 "Konserveringsmiddel til metalskærevæske, BPR-reg. nr. 578-30-2-x(3). Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)".

b) Oplysning om præparattype: "væske" 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/holderen 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.

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

| | |
|-------------------|-----------------|
| Troyshield F20 | Market area: DK |
| Fungitrol L20 DPG | Market area: DK |
| Troyshield F20 | Market area: AT |
| Troyshield F20 | Market area: BE |
| | |

| | |
|----------------|-----------------|
| Troyshield F20 | Market area: BG |
| Troyshield F20 | Market area: CZ |
| Troyshield F20 | Market area: FI |
| Troyshield F20 | Market area: FR |
| Troyshield F20 | Market area: DE |
| Troyshield F20 | Market area: HU |
| Troyshield F20 | Market area: IT |
| Troyshield F20 | Market area: LU |
| Troyshield F20 | Market area: NL |
| Troyshield F20 | Market area: NO |
| Troyshield F20 | Market area: PL |
| Troyshield F20 | Market area: PT |
| Troyshield F20 | Market area: RO |
| Troyshield F20 | Market area: SK |
| Troyshield F20 | Market area: SI |
| Troyshield F20 | Market area: ES |

| | |
|---|-----------------|
| Troyshield F20 | Market area: SE |
| Fungitrol L20 DPG | Market area: SE |
| Troyshield F20 | Market area: CH |
| Troyshield F20 | Market area: GB |
| Authorisation number <small>(R4BP 3 asset reference number - National Authorisation)</small> DK-0016529-0002 1-2 | |

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|--|------------|------------------|------------|-----------|-------------|
| 3-iodo-2-propynylbutylcarbamate (IPBC) | | Active Substance | 55406-53-6 | 259-627-5 | 20 |

1. Meta SPC administrative information

1.1. Meta SPC identifier

IPBC 30

1.2. Suffix to the authorisation number

1-3

1.3 Product type(s)

PT13 - Working or cutting fluid preservatives (Preservatives)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|--|------------|------------------|------------|-----------|-------------|
| 3-iodo-2-propynylbutylcarbamate (IPBC) | | Active Substance | 55406-53-6 | 259-627-5 | 30 - 30 |

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Harmful if swallowed.
Harmful if inhaled.
Causes serious eye damage.
Causes skin irritation.
Causes damage to organs Larynx through prolonged or repeated exposure inhalation.
Very toxic to aquatic life with long lasting effects.
May cause an allergic skin reaction.

Precautionary statements

Wear protective gloves.
Wear protective clothing.
Wear face protection.
Wear eye protection.
Avoid release to the environment.
Do not breathe vapours.
Do not breathe mist.

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.

Dispose of contents to in accordance with local/regional/national/international regulation.

4. Authorised use(s) of the meta SPC

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) | <p>Scientific name: Yeasts Common name: Yeasts Development stage: vegetative cells</p> <p>Scientific name: Fungi Common name: Mould fungi Development stage: vegetative cells</p> |
| 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 systems 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). Tank-side addition to a metal working fluid in use (curative treatment): 0.017-0.05% (equivalent to 0.005-0.015% IPBC).</p> |

Application rate(s) and frequencies

Application Rate: Tank-side addition: 0.017 - 0.05 % 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.

Curative use:
1 additional tank side application to the metal working fluid in the use phase (in case of contamination).

Category(ies) of users

Industrial
Professional

Pack sizes and packaging material

5-30 kg Pail, Plastic HDPE, Screw cap HDPE

200-230 kg Drum, Plastic HDPE, Screw cap HDPE

1000-1100 kg IBC, Plastic HDPE, Screw cap HDPE

4.1.1 Use-specific instructions for use

The product is a liquid organic fungicide preparation 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).
The metal working fluid concentrate must be diluted by the user with water before use.
Addition to the diluted metal working fluid in use: The product can be added to metal working fluids in use by adding it to the storage tank of the metal working fluid in use. It is recommended that the optimum biocide concentration and compatibility with individual formulations be 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 vapor or mist. 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. Flush contaminated skin with plenty of 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. Wash clothing before reuse.

Clean shoes thoroughly before reuse.

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: Stop leak if without risk. Move containers from spill area. Dilute with water and mop up or absorb with an inert dry material. Place contaminated water or absorbant material in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor. Wear gloves while cleaning.

Large spill: Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Wear gloves while cleaning.

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

Waste treatment methods

Product: Dispose of in accordance with the European Directives on waste and hazardous waste. Do not contaminate ponds, waterways or ditches with chemical or used container. Container hazardous when empty. Dispose of in accordance with local regulations.

Contaminated packaging: Empty remaining contents. Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal.

Do not re-use empty containers.

Do not burn, or use a cutting torch on, the empty drum.

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: 5 – 25 °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 of the meta SPC

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, GHS07, 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.

Farlig ved indånding.

Forårsager hudirritation.

Kan forårsage allergisk hudreaktion.

Forårsager alvorlig øjensskade.

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/øjensbeskyttelse/ansigtsbeskyttelse."

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

"

Undgå udledning til miljøet.

Udslip opsamles.

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 0,017-0,05 % (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 utilgængeligt for børn.
 Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.
 Emballagen må ikke genanvendes”
 Farepiktogrammet GHS05, GHS07, 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 deklaraionsfeltet:
 a) Teksten "Konserveringsmiddel til metalkærevæske, BPR-reg.nr. 578-30-3-x(3). Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)".
 b) Oplysning om præparattype: "væske" 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.

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

| | | |
|---------------|-------------------|-----------------|
| Trade name(s) | Troyshield FX40 | Market area: DK |
| | Fungitrol L30 DPG | Market area: DK |
| | Troyshield FX40 | Market area: AT |

| | |
|-----------------|-----------------|
| Troyshield FX40 | Market area: BE |
| Troyshield FX40 | Market area: BG |
| Troyshield FX40 | Market area: CZ |
| Troyshield FX40 | Market area: FI |
| Troyshield FX40 | Market area: FR |
| Troyshield FX40 | Market area: DE |
| Troyshield FX40 | Market area: HU |
| Troyshield FX40 | Market area: IT |
| Troyshield FX40 | Market area: LU |
| Troyshield FX40 | Market area: NL |
| Troyshield FX40 | Market area: NO |
| Troyshield FX40 | Market area: PL |
| Troyshield FX40 | Market area: PT |
| Troyshield FX40 | Market area: RO |
| Troyshield FX40 | Market area: SK |
| Troyshield FX40 | Market area: SI |

| | |
|--|-----------------|
| Troyshield FX40 | Market area: ES |
| Troyshield FX40 | Market area: SE |
| Fungitrol L30 DPG | Market area: SE |
| Troyshield FX40 | Market area: CH |
| Troyshield FX40 | Market area: GB |
| Authorisation number (R4BP 3 asset reference number - National Authorisation) DK-0016529-0003 1-3 | |

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|--|------------|------------------|------------|-----------|-------------|
| 3-iodo-2-propynylbutylcarbamate (IPBC) | | Active Substance | 55406-53-6 | 259-627-5 | 30 |

1. Meta SPC administrative information

1.1. Meta SPC identifier

IPBC 100

1.2. Suffix to the authorisation number

1-4

1.3 Product type(s)

PT13 - Working or cutting fluid preservatives (Preservatives)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

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

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

GR - Granule

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Toxic if inhaled.
Harmful if swallowed.
Causes serious eye damage.
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.

Precautionary statements

Do no 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) of the meta SPC

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) | <p>Scientific name: Yeasts Common name: Yeasts Development stage: vegetative cells</p> <p>Scientific name: Fungi Common name: Mould fungi Development stage: vegetative cells</p> |
| 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> |
| <p>Application rate(s) and frequencies</p> | <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> |
| <p>Category(ies) of users</p> | <p>Industrial</p> <p>Professional</p> |
| <p>Pack sizes and packaging material</p> | <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 °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 of the meta SPC

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 metalskærevæsker

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

Må kun anvendes i doseringer på 0,005-0,015 % (w/w) ved behandling af metalskærevæsker 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 metalskærevæskekoncentrater skal producenten sikre, at der medfølger det behandlede metalskærevæskekoncentrat instruktioner for dosering, der sikrer en effektiv koncentration af aktivstoffet i metalskærevæskens under brug, men således at koncentrationen af IPBC i metalskærevæskens 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 vejtrækningen 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 metalkærevæske, 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.

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

| | |
|------------------|-----------------|
| Polyphase P100G | Market area: DK |
| Troyshield F100G | Market area: BE |
| Fungitrol 400G | Market area: AT |
| Fungitrol 400G | Market area: BG |

| | |
|------------------|-----------------|
| Fungitrol 400G | Market area: CZ |
| Troyshield F100G | Market area: FI |
| Fungitrol 400G | Market area: FR |
| Fungitrol 400G | Market area: DE |
| Fungitrol 400G | Market area: HU |
| Fungitrol 400G | Market area: IT |
| Fungitrol 400G | Market area: LU |
| Fungitrol 400G | Market area: NL |
| Fungitrol 400G | Market area: NO |
| Fungitrol 400G | Market area: PL |
| Fungitrol 400G | Market area: PT |
| Fungitrol 400G | Market area: RO |
| Fungitrol 400G | Market area: SK |
| Fungitrol 400G | Market area: SI |
| Fungitrol 400G | Market area: ES |
| Fungitrol 400G | Market area: CH |

| | |
|---------------------|-----------------|
| Fungitrol 400G | Market area: SE |
| Fungitrol 400G | Market area: GB |
| Troyshield F100G | Market area: DK |
| Polyphase P100G | Market area: SE |
| DK-0016529-0004 1-4 | |

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

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