### **ANNEX**

### SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

### **SOFAST**

### **Product type(s)**

PT18: Insecticides, acaricides and products to control other arthropods

**Authorisation number:** UOS2505350

**R4BP asset number:** IS-0035054-0000

### 1. ADMINISTRATIVE INFORMATION

### 1.1. Trade name(s) of the product

Trade name(s)	SOFAST
	Imidafast
	Fly Speed Killer

### 1.2. Authorisation holder

	Name	Sharda Cropchem España S.L.
Name and address of the authorisation holder	Address	Edificio Atalayas Business Center Carril Condomina N°3 Planta 12 30006 Murcia Spain
Authorisation number		UOS2505350
R4BP asset number		IS-0035054-0000
Date of the authorisation		06/06/2025
Expiry date of the authorisation		26/06/2034

### **1.3.** Manufacturer(s) of the product

Name of manufacturer	Sharda Worldwide Exports Pvt Ltd
Address of manufacturer	Dominic Holm, 29th Road, Bandra 400050 Mumbai I ndia
	Sharda Worldwide Exports Pvt Ltd site 1 EKOPREVE NT KFT - Komló u. 10. 1222 Budapest Hungary

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

Active substance	imidacloprid
Name of manufacturer	Sharda Worldwide Exports Pvt Ltd
Address of manufacturer	Dominic Holm, 29th Road, Bandra 400050 Mumbai I ndia
Location of manufacturing sites	Sharda Worldwide Exports Pvt Ltd site 1 HEBEI VEY ONG BIO-CHEMICAL CO.LTD - 393 East Heping R oad - Shijizhuang China

Active substance	cis-tricos-9-ene (Muscalure)
Name of manufacturer	Sharda Worldwide Exports Pvt Ltd
Address of manufacturer	Dominic Holm, 29th Road, Bandra 400050 Mumbai I ndia
Location of manufacturing sites	Sharda Worldwide Exports Pvt Ltd site 1 HEBEI VEY ONG BIO-CHEMICAL CO.LTD - 393 East Heping R oad - Shijizhuang China

Active substance	cis-tricos-9-ene (Muscalure)
Name of manufacturer	Denka International Holding B.V.
Address of manufacturer	Hanzeweg 1 NL-3771 NG Barneveld Netherlands (the

Location of manufacturing sites	Denka International Holding B.V. site 1 Hanzeweg 1
	NL-3771 NG Barneveld Netherlands (the)

### 2. PRODUCT COMPOSITION AND FORMULATION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
imidacloprid	(2E)-1-[(6- chloropyridin-3- yl) methyl]-N- nitroimidazolidin- imine	Active substance	138261-41-3	428-040-8	0,52 % (w/w)
cis-tricos-9-ene ( Muscalure)	cis-Tricos-9-ene; (Z)-Tricos-9-ene	Active substance	27519-02-4	248-505-7	0,1 % (w/w)

### 2.2. Type(s) of formulation

Water-dispersable granules

### 3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H410: Very toxic to aquatic life with long lasting effe
	cts.
	EUH208: Contains cis-Tricos-9-ene. May produce an
	allergic reaction.
Precautionary statements	P273: Avoid release to the environment.
	P391: Collect spillage.
	P501: Dispose of container to according to national le gislation.
	P501: Dispose of container to according to national le gislation.

### 4. AUTHORISED USE(S)

### 4.1. Use description

Table 1. Professional use: brushing on cardboards

Product type	PT18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide
Target organism(s) (including development stage)	Scientific name: Muscidae: Muscidae: Common name: Flies Development stage: imagines; adults
Field(s) of use	Indoor use (industrial/commercial premises; households/ private areas; public areas)
Application method(s)	Method: Brushing on cardboards  Detailed description: In order to treat a room/building with a floor surface of 100 m2 200 g of the product are dispersed in 150mL water and applied to cardboard sheets with a total surface of 1m2. The cardboard sheets are then distributed in the area to be treated.
Application rate(s) and frequency	Application Rate: In order to treat a room/building with a floor surface of 100 m2 200 g of the product are dispersed in 150mL water and applied to cardboard sheets with a total surface of 1m2.  Number and timing of application: Up to 6 applications per year.
Category(ies) of users	professional
Pack sizes and packaging material	10g bag HDPE  10g, 50g, 100g bottle HDPE or PP  300g, 350g bottle HDPE  1kg, 2kg bucket PP or Polyester with LDPE sealing film in a cardboard case (Secondary packaging for complex bag)  50g, 300g, 1kg, 2kg can PP or Polyester with LDPE sealing film in a cardboard case  1kg, 2kg complex bag (foil of complex material made of LDPE + polypropylene or polyester or paper)

#### **4.1.1.** Use-specific instructions for use

- 1) Mix well before application. Stir until homogenisation is achieved, approximately 2 minutes.
- 2) Use the dispersion within 8 hours after mixing.
- 3) Place cardboards where flies prefer to rest.
- 4) Check the cardboards every week, renew the application when there is no product or the cardboards are covered with dirt.
- 5) Alternate products containing active substances with different mode of action, (to remove resistant individuals from the population).
- 6) Apply only on cardboards which are then to be fixed to walls or ceilings where flies prefer to rest.
- 7) For application of the dispersion on cardboards the applicator must use a disposable brush.
- 8) The area, where mixing/loading and the application to cardboards takes place, must be covered with a disposable plastic sheet in order to avoid contamination of adjacent surfaces and floor.
- 9) For the mixing/loading and the application step the applicator must wear a disposable protective coverall (at least type 6, EN 13034) to avoid emissions to the sewer system due to washing of contaminated clothes.
- 10) Do not let the product or its residues or brushing sludge enter soil, water courses or the sewer systems.
- 11) Do not clean the cardboards.
- 12) Dead flies must be collected immediately by dry cleaning methods only (i.e. vacuum cleaner or disposable cloth) with subsequent disposal via solid waste.

### 4.1.2. Use-specific risk mitigation measures

- 1) Attach treated cardboards inaccessible for children, pets, livestock animals and other non-target animals.
- 2) Children and pets should not be present during mixing/loading and the application to cardboards.
- 3) When applying the product on cardboards leave an untreated area around the edge.
- 4) When fixing the treated cardboards to walls or ceilings or collecting them for disposal touch only the untreated area around the edge.
- 5) The following risk mitigation measures without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work shall be applied
- Wearing of chemical resistant gloves meeting the requirements of European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for the application method brushing on cardboards.
- Wear a disposable protective coverall (at least type 6, EN 13034)

# 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

None

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

Disposal of contaminated plastic sheets, disposable clothes and cardboards after use and all other waste (brush cleaning water, material used for spill cleaning, etc...) to residual waste as specified by the local disposer.

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

None

## 4.2. Use description

Table 2. Professional use: bait application in disposable shallow dishes

Product type	PT18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide
Target organism(s) (including development stage)	Scientific name: Muscidae: Muscidae: Common name: Flies Development stage: imagines; adults
Field(s) of use	indoor use industrial/commercial premises; households/ private areas; public areas
Application method(s)	Method: bait application  Detailed description: 20g for 10m2 floor area to be treated; one bait point (disposable shallow dishes) per 10m2 floor area.
Application rate(s) and frequency	Application Rate: 20g for 10m2 floor area to be treated; one bait point (disposable shallow dishes) per 10m2 floor area.  Number and timing of application: Up to 6 applications per year.
Category(ies) of users	professional
Pack sizes and packaging material	10g bag HDPE  10g bottle HDPE or PP  50g, 100g bottle HDPE or PP with dosing spoon/beaker  300g, 350g bottle HDPE with dosing spoon/beaker  1kg, 2kg bucket PP or Polyester with LDPE sealing film in a cardboard case with dosing spoon/beaker (Secondary packaging for complex bag)  50g, 300g, 1kg, 2kg can PP or Polyester with LDPE sealing film in a cardboard case with dosing spoon/beaker  1kg, 2kg complex bag (foil of complex material made of LDPE + polypropylene or polyester or paper) with dosing spoon/beaker

#### 4.2.1. Use-specific instructions for use

- 1) Place granules in disposable shallow dishes avoiding the formation of piles.
- 2) Use the included dosing spoon/beaker when measuring the granules.
- 3) Create bait points with 20g granules every 10m², only up high (shelves, ledges, walls).
- 4) It is advisable to moisten the granules for greater efficiency.
- 5) Check bait points every 2 to 3 days.
- 6) Remove application when the granules are covered with dust.
- 7) The people responsible for cleaning the treated areas are to be instructed by the professional user on the use instructions to ensure that the product does not reach the sewer system.
- 8) Use only disposable shallow dishes and the dosing spoon to place the granular bait.
- 9) Product spills, residues and dead flies must be collected immediately by dry cleaning methods only (i.e., vacuum cleaner or disposable cloth) with subsequent disposal via solid waste.
- 10) Do not wet wash the surfaces contaminated with the product or its residues. In case that the surfaces are cleaned, use disposable wet wipes with subsequent disposal via solid waste.
- 11) Ensure that spills from the application devices are avoided by un-intentional movement of the product through e.g. wind, humans or larger animals.
- 12) Do not wet clean the dosing spoon and the disposable shallow dishes.
- 13) Collect product residues, product spills and all other waste for disposal in accordance with local requirement after treatment.
- 14) Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.

#### 4.2.2. Use-specific risk mitigation measures

- 1) Place product out of the reach of children, birds, pets, farm animals and other non-target animals.
- 2) Place product away from food, drink and feed, as well as from utensils or surfaces that have contact with these.

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

None

# 4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

None

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

None

### 4.3. Use description

# Table 3. Professional use in livestock facilities: brushing on cardboards

Product type	PT18: Insecticides, acaricides and products to control other
	arthropods

Where relevant, an exact description of the authorised use	Insecticide
Target organism(s) (including development stage)	Scientific name: Muscidae: Muscidae: Common name: Flies Development stage: imagines; adults
Field(s) of use	indoor use
Application method(s)	livestock facilities  Method: Brushing on cardboards  Detailed description:
	In order to treat a room/building with a floor surface of 100 m2 200 g of the product are dispersed in 150mL water and applied to cardboard sheets with a total surface of 1m2. The cardboard sheets are then distributed in the area to be treated.
Application rate(s) and frequency	Application Rate: In order to treat a room/building with a floor surface of 100 m2 200 g of the product are dispersed in 150mL water and applied to cardboard sheets with a total surface of 1m2. The cardboard sheets are then distributed in the area to be treated.
	Number and timing of application: Up to 6 applications per year. It takes up to 3 weeks after treatment for the biocidal product to efficiently control fly populations.
Category(ies) of users	professional
Pack sizes and packaging material	10g bag HDPE
	10g, 50g, 100g bottle HDPE or PP
	300g, 350g bottle HDPE
	1kg, 2kg bucket PP or Polyester with LDPE sealing film in a cardboard case (Secondary packaging for complex bag)
	50g, 300g, 1kg, 2kg can PP or Polyester with LDPE sealing film in a cardboard case
	1kg, 2kg complex bag (foil of complex material made of LDPE + polypropylene or polyester or paper)

### **4.3.1.** Use-specific instructions for use

- 1) Mix well before application. Stir until homogenisation is achieved, approximately 2 minutes.
- 2) Use the dispersion within 8 hours after mixing.
- 3) Place cardboards where flies prefer to rest.
- 4) Check the cardboards every week and renew the application when there is no product or the cardboards are covered with dirt.
- 5) It is recommendable to complement the treatment in livestock facilities at the beginning of the fly season with a larvicide product.

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- 6) The use of biocidal products can be combined with other sanitation measures (e.g. frequent removal of dung) or non-chemical means of control (for example biological, including the use of parasitoids) within an integrated fly control program.
- 7) Fly infestation in animal housings can be estimated by monitoring methods (e.g. monitoring of (re)-appearance of larvae in the manure or adult fly population with glue strips) prior to chemical treatment.
- 8) Apply only on cardboards which are then to be fixed to walls or ceilings where flies prefer to rest.
- 9) For application of the dispersion on cardboards the applicator must use a disposable brush.
- 10) The area, where mixing/loading and the application to cardboards take place, must be covered with a disposable plastic sheet in order to avoid contamination of adjacent surfaces and floor.
- 11) For the mixing/loading and the application step the applicator must wear a disposable protective coverall (at least type 6, EN 13034) to avoid emissions to the sewer system due to washing of contaminated clothes.
- 12) Do not let the product or its residues or brushing sludge enter soil, water courses or the sewer systems.
- 13) Do not clean the cardboards.
- 14) Remove all pieces of treated cardboards before cleaning and/or disinfectant events in livestock facilities.
- 15) Do not apply the biocidal product directly on manure/slurry.

#### 4.3.2. Use-specific risk mitigation measures

- 1) Attach treated cardboards inaccessible for children, pets, livestock animals and other non-target animals.
- 2) Children and pets should not be present during mixing/loading and the application to cardboards.
- 3) When applying the product on cardboards leave an untreated area around the edge.
- 4) When fixing the treated cardboards to walls or ceilings or collecting them for disposal touch only the untreated area around the edge.
- 5) Place cardboards treated with biocidal product out of reach of livestock animals.
- 6) The following risk mitigation measures without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work shall be applied
- Wearing of chemical resistant gloves meeting the requirements of European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required for the application method brushing on cardboards.
- Wear a disposable protective coverall (at least type 6, EN 13034).

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

None

# 4.3.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

Disposal of contaminated plastic sheets, disposable clothes and cardboards after use and all other waste (brush cleaning water, material used for spill cleaning, etc...) to residual waste as specified by the local disposer.

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

None

### 4.4. Use description

Table 4. Professional use in livestock facilities: bait application in bait stations

Product type	PT18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide
Target organism(s) (including development stage)	Scientific name: Stomoxys calcitrans Common name: stable flies Development stage: imagines; adults
Field(s) of use	indoor use
Amaliantian mathad(a)	livestock facilities
Application method(s)	Method: bait application  Detailed description: 20g for 10m2 floor area to be treated; One bait station per 10m2 floor area.
Application rate(s) and frequency	Application Rate: 20g for 10m2 floor area to be treated; One bait station per 10m2 floor area.
	Number and timing of application: Up to 6 applications per year. It takes up to 4 weeks after treatment for the biocidal product to efficiently control stable fly populations.
Category(ies) of users	professional
Pack sizes and packaging material	10g bag HDPE
	10g bottle HDPE or PP
	50g, 100g bottle HDPE or PP with dosing spoon/beaker
	300g, 350g bottle HDPE with dosing spoon/beaker
	1kg, 2kg bucket PP or Polyester with LDPE sealing film in a cardboard case with dosing spoon/beaker (Secondary packaging for complex bag)
	50g, 300g, 1kg, 2kg can PP or Polyester with LDPE sealing film in a cardboard case with dosing spoon/beaker
	1kg, 2kg complex bag (foil of complex material made of LDPE + polypropylene or polyester or paper) with dosing spoon/beaker

### **4.4.1.** Use-specific instructions for use

1) Use the included dosing spoon/beaker when measuring the granules.

- 2) Place bait stations with 20g granules every 10m<sup>2</sup>, only up high (shelves, ledges, walls).
- 3) It is advisable to moisten the granules for greater efficiency.
- 4) Check bait stations every 2 to 3 days.
- 5) Remove application when the granules are covered with dust.
- 6) It is recommendable to complement the treatment in livestock facilities at the beginning of the fly season with a larvicide product.
- 7) The use of biocidal products can be combined with other sanitation measures (e.g. frequent removal of dung) or non-chemical means of control (for example biological including the use of parasitoids) within an integrated fly control program.
- 8) Fly infestation in animal housings can be estimated by monitoring methods (e.g. monitoring of (re)appearance of larvae in the manure or adult fly population with glue strips) prior to chemical treatment.
- 9) Apply only in recommended bait stations (specific for flies). Use the dosing spoon to place the granular bait.
- 10) Do not wet clean the dosing spoon and the bait stations.
- 11) Do not apply the biocidal product directly on manure/slurry.
- 12) Remove all bait stations before cleaning and/or disinfectant events in livestock facilities.

### 4.4.2. Use-specific risk mitigation measures

- 1) Place product out of the reach of children, birds, pets, farm animals and other non-target animals.
- 2) Place product away from food, drink and feed, as well as from utensils or surfaces that have contact with these.
- 3) Place bait stations out of reach of livestock animals.
- 4) Do not use the product in the presence of and to control house flies (*Musca domestica*) to avoid the development of resistance (as a sufficient efficacy has only been demonstrated against stable flies (*Stomoxys calcitrans*)).

# **4.4.3.** Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment None

# 4.4.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

None

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

None

### 5. GENERAL DIRECTIONS FOR USE<sup>1</sup>

#### **5.1.** Instructions for use

- 1) Start treatment at the beginning of fly season to prevent massive proliferation.
- 2) Avoid continuous use of the product.
- 3) In order to avoid the occurrence of resistance to any active ingredient, products with different modes of action should be used in alternation and the frequent repeated use of the same active substance should be avoided.
- 4) Inform the authorisation holder if the treatment is ineffective.
- 5) This biocidal product contains the active substance Imidacloprid which is dangerous to bees.

#### 5.2. Risk mitigation measures

- 1) Always read the label or leaflet before use and follow all the instructions provided.
- 2) Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets.
- 3) Clean up spills of the biocidal product immediately.
- 4) Avoid any unnecessary contact to the product. Misuse may cause health damage
- 5) Do not empty into drains.
- 6) Do not let the product, product waste or washing water from cleaning equipment (e.g. mugs, brush) enter into water courses or the sewer system.
- 7) The product can be applied in the presence of animals, if contact with the biocidal product is avoided.

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

- 1) IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.
- 2) IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation or rash occur: Get medical advice.
- 3) IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
- 4) IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.

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

- 1) Keep only in original container.
- 2) Do not mix with other wastes.
- 3) Residues of the biocidal product and all other contaminated waste (e.g. disposable plastic sheet, shallow dishes, dosing spoon and brush; material to collect product spills; dead flies) must be disposed of in accordance with the Waste Framework Directive (2008/98/EG) and the European Waste Catalogue (EWC) as well as national and regional regulations.
- 4) Containers containing residues of the product have to be handled accordingly:
- European waste catalogue (EWC) Waste code 15 01 10\*: packaging containing residues of or contaminated by dangerous substances
- European waste catalogue (EWC) Waste code 20 01 19\*: pesticides

<sup>&</sup>lt;sup>1</sup>Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

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

- Shelf-life: 36 months.
   Protect from direct light.
- 3) Store in a dry place.4) Do not store near food, drinks and feed.

#### 6. OTHER INFORMATION

- 1) The product contains a bittering agent.
- 2) According to the information provided the product contains nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012.

The signal word, hazard- and precautionary statements shall be in Icelandic on the product label in accordance with Article 4 of the National Regulation No 878/2014 and Article 32 of the Chemicals Act No 61/2013.

### Signal word:

#### VARÚĐ

**Hazard statements:** 

H410 Mjög eitrað lífi í vatni, hefur langvinn áhrif.

EUH 208 Inniheldur cis-tríkós-9-en. Getur framkallað ofnæmisviðbrögð.

Precautionary statements:

P273 Forðist losun út í umhverfi.

P391 Safnið upp því sem hellist niður.

P501 Fargið innihaldi í samræmi við landsbundnar reglur.

P501 Fargið íláti í samræmi við landsbundnar reglur.