Summary of product characteristics for a biocidal product

Product name: FAM - SUB FAMILY - TRADE NAMES

Product type(s): PT03 - Veterinary hygiene (Disinfectants)

Authorisation number: 798-1

R4BP 3 asset reference number: DK-0012902-0001

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Administrative information

1.1. Trade names of the product

FAM	
Biocid	
Vanodine	
Vanodin	
Vanodine FAM	
Antigermen Potente	

1.2. Authorisation holder

Name and address of the authorisation holder

Name	Evans Vanodine Europe	
Address	6-9 Trinity Street D02 EY47 Dublin 2 Ireland	

Authorisation number

R4BP 3 asset referenc	е
number	

Date of the authorisation

Expiry date of the authorisation

DK-0012902-0001
29/03/2019
06/03/2029

1.3. Manufacturer(s) of the biocidal products

798-1 1-1

Name of the manufacturer	Evans Vanodine International	
Address of the manufacturer	Brierley Road, Walton Summit PR58AH Preston, Lancashire United Kingdom	
Location of manufacturing sites	Brierley Road, Walton Summit PR58AH Preston, Lancashire United Kingdom	

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

Active substance	1319 - Iodine		
Name of the manufacturer	ACF Minera S.A.		
Address of the manufacturer	San Martin No 499 None Iquique Chile		
Location of manufacturing sites	Lagunas mine None Pozo Almonte Chile		
Active substance	1319 - Iodine		
Name of the manufacturer	SQM S.A.		
Address of the manufacturer	Los Militares 4290, Piso 4, Las Condes None Santiago Chile		
Location of manufacturing sites	Nueva Victoria plant, Pedro de Valdivia plant None None Chile		
Active substance	1319 - Iodine		
Name of the manufacturer	Cosayach Nitratos S.A.		
Address of the manufacturer	Hnos Amunátegui 178 None Santiago Chile		
Location of manufacturing sites	CosayA. Compania de Salitre y Yodo None Not reported Chile		

Active substance	1319 - Iodine		
Name of the manufacturer	ISE Chemicals Corporation		
Address of the manufacturer	3-1, Kyobshi 1-Chrome, Chuo-ku, None Tokyo Japan		
Location of manufacturing sites	Shirasato Plant, 3695 Kitaimaizumi None Oamishirasato City Japan		

2. Product composition and formulation

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	2,179
Alcohol Ethoxylate	C9-11 Alcohol Ethoxylate (8EO)		68439-46-3	614-482-0	18,575
Sulphuric Acid	Sulphuric Acid		7664-93-9	231-639-5	7,995
Phosphoric Acid	Trihydroxidooxido- phosphorus		7664-38-2	231-633-2	12,495

2.2. Type of formulation

SL - Soluble concentrate

3. Hazard and precautionary statements

Hazard statements	Causes severe skin burns and eye damage.		
	Harmful to aquatic life with long lasting effects.		
	May be corrosive to metals.		
Precautionary statements			
Precautionary statements	If medical advice is needed, have product container or label at hand.		
Precautionary statements	If medical advice is needed, have product container or label at hand. Store locked up.		
Precautionary statements			

Do not breathe mist.

Avoid release to the environment.

Wear protective gloves.

Wear protective clothing.

Wear eye protection.

Wear face protection.

IF SWALLOWED:Rinse mouth.Do NOT induce vomiting.

IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with water.

IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with shower.

IF INHALED:Remove person to fresh air and keep comfortable for breathing.

IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a POISON CENTER/doctor.

Wash contaminated clothing before reuse.

Dispose of contents to in accordance with local regulations.

Dispose of container to in accordance with local regulations..

4. Authorised use(s)

4.1 Use description

Use 1 - Use # 1 (FAM) - animal accommodation surface disinfection - spray or foam application

Product type

Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

PT03 - Veterinary hygiene (Disinfectants)

Products used to disinfect the materials and surfaces associated with the housing of animals.

Scientific name: Bacteria Common name: Bacteria Development stage: All

Scientific name: Other Viruses Common name: Viruses Development stage: All

Scientific name: Yeast Common name: Yeast Development stage: All

Scientific name: Mycobacteria Common name: Mycobacteria Development stage: All

Field(s) of use

Indoor

Indoor

Application method(s)

Spraying -

Decant or dispense (using dispensing equipment) the concentrated product and dilute with water. Fill the reservoir of the knapsack sprayer (low pressure spray) with the diluted concentrate.

Foaming -

The concentrated products are diluted by decanting or by dispensing (using dispensing equipment). The diluted concentrate is filled into the reservor of a knapsacksprayer (low pressure foam).

Application rate(s) and frequencies

300 mL/m2 (dilute solution) - Dilution ratios - FAM 1:75 -

The disinfection of animal housing takes places as follows:

- Dairy cattle: Once per year
- Veal calves: Every 17-19 weeks
- Fattening pigs: Twice per year
- Laying hens: Once per 12 -18 months
- Broiler: Every 7 weeks
- Turkeys: Twice per year
- Ducks: Every 8 weeks
- Geese: Twice per year
- Sheep: Once per year
- Goats: Once per year

300 mL/m2 (dilute solution) - Dilution ratios - FAM 1:75 -

The disinfection of animal housing takes places as follows:

- Dairy cattle: Once per year
- Veal calves: Every 17-19 weeks
- Fattening pigs: Twice per year
- Laying hens: Once per 12 -18 months
- Broiler: Every 7 weeks
- Turkeys: Twice per year
- Ducks: Every 8 weeks
- Geese: Twice per year
- Sheep: Once per yearGoats: Once per year
- Category(ies) of users

Professional

Pack sizes and packaging material

Containers such as (bottles, jerry cans, drums, IBC) made from HDPE - 1 - 1000 Litres

4.1.1 Use-specific instructions for use

Clean and rinse surfaces prior to disinfection

Decant or dispense (using dispensing equipment) the concentrated product and dilute with water. Fill the reservoir of the knapsack sprayer (low pressure spray) with the diluted concentrate. Spray the disinfectant making sure surfaces are thoroughly wetted and leave to dry for 30-minutes, porous surfaces should be allowed to dried for a minimum of 4 hours. After disinfection, empty and clean the reservoir and the spray equipment by rinsing with water.

Dilution ratios - FAM 1:75

4.1.2 Use-specific risk mitigation measures

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

A protective coverall (at least type 4, EN 14605) which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information).

The use of eye protection during handling of the product is mandatory.

Feed and water troughs are to be covered during biocidal treatment

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

See Directions for use.

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

See Directions for use.

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

See Directions for use.

4.2 Use description

Use 2 - Use # 2 (FAM) - animal accommodation equipment disinfection - immersion

Product type

Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

PT03 - Veterinary hygiene (Disinfectants)

Products used to disinfect the materials and surfaces associated with the housing of animals.

Scientific name: Other: Bacteria Common name: bacteria Development stage: All

Scientific name: other yeast Common name: Yeasts Development stage: all

Scientific name: Viruses Common name: Viruses Development stage: all

Scientific name: Mycobacteria Common name: Mycobacteria Development stage: All

Field(s) of use

Indoor

Outdoor

Indoor and outdoor

Application method(s)

Open system: immersion -

The concentrated products are diluted by decanting or by dispensing (using dispensing equipment). The diluted concentrate is filled in a clean container and the equipment (e.g. buckets, cages, hatchery trays, drinkers, crates) is placed in the solution. The equipment is left for at least 30 minutes before removing and allowing equipment to drain and dry.

Application rate(s) and frequencies

Immersere for 30-minutes in 100 litres of diluted solution - Dilution ratios - FAM 1:75 - The equipment disinfection in animal accomodation by immersion takes place indoor or outdoor by professional workers as follows:

- Broiler: Every 7 weeks
- Ducks: Every 8 weeks

Category(ies) of users

Professional

Pack sizes and packaging material

Containers such as (bottles, jerry cans, drums, IBC) made from HDPE - 1 -1 000 Litres

4.2.1 Use-specific instructions for use

Clean and rinse surfaces prior to disinfection

Decant or dispense (using dispensing equipment) the concentrated product and dilute with water. Fill a clean container with the diluted concentrate and place equipment (e.g. buckets, cages, hatchery trays, drinkers, crates) in the solution, leave for at least 30 minutes before removing and allowing equipment to drain and dry. Dispose the disinfection solution into STP. Dilution ratios – FAM 1:75

4.2.2 Use-specific risk mitigation measures

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

A protective coverall (at least type 6, EN 13034) shall be worn.

The use of eye protection during handling of the product is mandatory.

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

See Directions for use.

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

See Directions for use.

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

See Directions for use.

4.3 Use description

Use 3 - Use # 3 (FAM) - disinfection of vehicles for transporting animals - spray application

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Products used to disinfect the materials and surfaces associated with transportation of animals.

Target organism(s) (including development stage)

Scientific name: bacteria Common name: bacteria Development stage: all

Scientific name: Viruses Common name: Viruses Development stage: all

Scientific name: yeast Common name: Yeasts Development stage: all

Scientific name: Mycobacteria Common name: Mycobacteria Development stage: All

Field(s) of use

Outdoor

Outdoor

Application method(s)

Spraying -

The concentrated products are diluted by decanting or by dispensing (using dispensing equipment). The diluted concentrate is filled into the reservoir of a knapsack sprayer (low pressure spray). The surfaces are sprayed with the disinfectant making sure that the surfaces are thoroughly wetted. The product is left on the surfaces until it has dried (porous surfaces should be dried for a minimum of 4 hours).

Application rate(s) and frequencies	300mL/m² diluted solution - Dilution ratios – FAM 1:75 - Generally, the vehicles for transporting animals are cleaned and disinfected with products which are not iodine-based. Only in in case of disease, the disinfection is done with iodine-based products.			
Category(ies) of users	Professional			
Pack sizes and packaging material	Containers such as (bottles, jerry cans, drums, IBC) made from HDPE - 1 - 1000 Litres			
4.3.1 Use-specific instruction	ns for use			
Clean and rinse surfaces prior to disinfection Decant or dispense (using dispensing equipment) the concentrated product and dilute with water. Fill the reservoir of the knapsack sprayer (low pressure spray) with the diluted concentrate. First, apply the disinfectant solution to the outside of the vehicle including wheel arches, tyres, mudguards and underside of the vehicle, starting at the top and working down. Thereafter, spray on the inside of the vehicle, starting at the top and working down to the bottom, ensuring that all surfaces including the floor are covered. After disinfection (at least 30-minutes), empty and clean the reservoir and the spray equipment by rinsing with water. Dilution ratios – FAM 1:75				
4.3.2 Use-specific risk mitiga	tion measures			
Wear protective chemical resistant gloves	s (glove material to be specified by the authorisation holder within the product information).			
A protective coverall (at least type 4, EN specified by the authorisation holder with	14605) which is impermeable for the biocidal product shall be worn (coverall material to be in the product information).			
The use of eye protection during handling of the product is mandatory.				
	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment			
See Directions for use.				
4.3.4 Where specific to the us packaging	se, the instructions for safe disposal of the product and its			
See Directions for use.				

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

See Directions for use.

4.4 Use description

Use 4 - Use # 4 (FAM) - disinfection of fish farm equipment - immersion

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Products used to disinfect the materials and surfaces associated with the housing of animals.

Target organism(s) (including development stage)

Scientific name: Bacteria Common name: Bacteria Development stage: all

Scientific name: Viruses Common name: Viruses Development stage: all

Scientific name: Yeast Common name: Yeasts Development stage: all

Scientific name: Mycobacteria Common name: Mycobacteria Development stage: All

Field(s) of use

Outdoor

Outdoor.

Application method(s)

Open system: immersion -

The concentrated products are diluted by decanting or by dispensing (using dispensing equipment). The diluted concentrate is filled a clean container and the equipment (e.g. buckets, cages, hatchery trays, drinkers, crates) is placed in the solution. The equipment is left for at least 30 minutes before removing and allowing equipment to drain and dry. For larger pieces of equipment such as fish holding tanks, the cleaned containers are filled with the disinfectant. The disinfectant is left for a minimum of 30 minutes, drained, rinsed with clean water and allowed to dry.

Application rate(s) and frequencies

500 L of diluted solution. - Dilution ratios - FAM 1:75 -

The disinfection of equipment in fish farming takes places once a week.

Category(ies) of users

Professional

Pack sizes and packaging material

Containers such as (bottles, jerry cans, drums, IBC) made from HDPE - 1 - 1000 Litres

4.4.1 Use-specific instructions for use

diluted concentrate and place equipment removing, drain, rinse the equipment with	ction uipment) the concentrated product and dilute with water. Fill a clean container with the (e.g. buckets, trays, fish nets, crates) in the solution, leave for at least 30 minutes before n clean potable water and allow to dry. For larger pieces of equipment such as fish holding ction solution, leave for a minimum of 30 minutes, drain, rinse with clean water and allow to
4.4.2 Use-specific risk mitiga	tion measures
Wear protective chemical resistant gloves	s (glove material to be specified by the authorisation holder within the product information).
A protective coverall (at least type 6, EN	13034) shall be worn.
The use of eye protection during handling	g of the product is mandatory.
-	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment
See Directions for use.	
4.4.4 Where specific to the us packaging	se, the instructions for safe disposal of the product and its
See Directions for use.	
4.4.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product torage
See Directions for use.	
4.5 Use description Use 5 - Use # 5 (FAM) – boot an	d wheel disinfection - dipping
Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Products used to disinfect the materials and surfaces associated with the housing or transportation of animals.
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: all

Outdoor

Outdoor

Field(s) of use

Application method(s)	Open system: dip treatment - The concentrated products are diluted by decanting or by dispensing (using dispensing equipment). The foot and wheel baths are filled with the diluted concentrate and placed at the entrances or exits. A two-minute contact time is to be ensured before moving from one area to another.
Application rate(s) and frequencies	Wheel bath (250 litres) – once per week (based upon the risk assessment up to 400 litres may be used). Boot bath (10 litres) – every day - Dilution ratios – FAM 1:75 - Wheel bath (250 litres) – once per week (based upon the risk assessment up to 400 litres may be used) Boot bath (10 litres) – every day
Category(ies) of users	Professional
Pack sizes and packaging material	Container, Plastic: HDPE , 5-1000 L
	ection juipment) the concentrated product and dilute with water. Fill foot/wheel bath with the diluted exits and ensure a two minute contact time before moving from one area to another. o a maximum volume of 400L
4.5.2 Use-specific risk mitigates Wear protective chemical resistant glove	ation measures s (glove material to be specified by the authorisation holder within the product information).
A protective coverall (at least type 6, EN	13034) shall be worn.
The use of eye protection during handlin	g of the product is mandatory.
<u>-</u>	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment

See Directions for use.

4.5.4 Where specific to the use, the instructions for safe disposal of the product and its packaging		
See Directions for use.		
5.5 Where specific to the use, the conditions of storage and shelf-life of the product nder normal conditions of storage		
See Directions for use.		
. General directions for use		
.1. Instructions for use		
See Authorised uses.		
.2. Risk mitigation measures		
See Authorised uses.		

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

Description of first aid measures

Inhalation: Unlikely route of exposure as the product does not contain volatile substances. If spray/mist has been inhaled, proceed as follows. Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing.

Ingestion: Do not induce vomiting. Rinse mouth thoroughly with water. Give plenty of water to drink. Get medical attention immediately.

Skin contact: Wash with plenty of water. Get medical attention promptly if symptoms occur after washing.

Eye contact: Rinse immediately with plenty of water. Remove any contact lenses and open eyelids wide apart. Continue to rinse. Get medical attention immediately.

Most important symptoms and effects, both acute and delayed

Inhalation: Irritation of nose, throat and airway.

Ingestion: May cause chemical burns in mouth and throat.

Skin contact: Burning pain and severe corrosive skin damage. May cause serious chemical burns to the skin. Eye contact: Severe irritation, burning and tearing. Prolonged contact causes serious eye and tissue damage.

Stability and reactivity:

Reactivity: Reacts with alkalis and generates heat.

Chemical stability: No particular stability concerns.

Conditions to avoid: Avoid exposure to high temperatures or direct sunlight.

Incompatible materials: Materials to avoid: Aluminium, Tin, Zinc and their alloys. Concentrated alkaline materials. Chlorine releasing materials will liberate toxic chlorine gas. Oxidising agents as Iodine vapour may be evolved.

Hazardous decomposition products: When heated, vapours/gases hazardous to health may be formed.

Environmental precautions

Spillages or uncontrolled discharges into watercourses must be reported immediately to the Environmental Agency or other appropriate regulatory body.

Flush away spillage with plenty of water. Small Spillages: Contain and absorb spillage with sand, earth or other non-combustible material. Collect and place in suitable waste disposal containers and seal securely.

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

At the end of the treatment used solutions can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an on-site waste water treatment plant.

Dispose unused product and the packaging in accordance with local and/or national requirements.

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

36 months shelf-life

Keep only in the original container in a cool, well-ventilated place. Store away from the following materials: Oxidising materials. Avoid exposure to high temperatures or direct sunlight.

6. Other information

Bilag 1

Oplysninger til etiket og brugsanvisning for produkter i Evans' lodine-based surface disinfection biocidal product family, MetaSPC "1" BPR-reg. nr. 798-1-1-x

[1]

i. Etiketten skal udformes i overensstemmelse med det godkendte resumé af det biocidholdige produkts egenskaber, jf. artikel 69, stk. 1, i biocidforordningen (Forordning (EU) nr. 528/2012), og CLP-Forordningen [2].

II. Det er udelukkende ansøgers/godkendelsesindehaverens ansvar, at etiket, mærkning og pakning lever op til lovens krav, jf. biocidforordningen artikel 69. Etiket og mærkning skal være på dansk.

Nedenstående tekst i afsnit III er bidrag til overholdelsen af reglerne og således kun en del af de krav, som stilles til blandt andet etiketten.

III. Etiketten skal indeholde nedenstående oplysninger. Oplysninger

i citationstegn skal angives ordret:

1) I hovedfeltet:

"Desinfektionsmiddel

Må kun anvendes erhvervsmæssigt til desinfektion af stalde og udstyr, dyretransporter, hav- og dambrugsudstyr samt støvle- og hjulbad.

2) I advarselsfeltet:

"FARE

Forårsager svære ætsninger af huden og øjenskader.

Skadelig for vandlevende organismer, med langvarige virkninger.

Kan ætse metaller.

Indånd ikke tåge.

Undgå udledning til miljøet."

"Bær beskyttelsestøj/øjenbeskyttelse/ansigtsbeskyttelse. Bær kemisk resistente beskyttelseshandsker ved brug af produktet".

Handskematerialet skal angives af godkendelsesindehaveren i produktdatabladet.

"Vask huden grundigt efter brug.

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

Må kun anvendes erhvervsmæssigt til desinfektion af stalde og udstyr, dyretransporter, hav- og dambrugsudstyr samt støvle- og hjulbad.

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

Må ikke tømmes i kloakafløb. Opbevares under lås og utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.

Levnedsmidler og foderstoffer må ikke forurenes.'

Farepiktogrammet GHS05.

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

Hvis der er brug for lægehjælp, medbring da beholderen eller etiketten.

I TILFÆLDE AF INDTAGELSE: Skyl munden. Fremkald IKKE opkastning.

VED KONTAKT MED HUDEN (eller håret): Alt tilsmudset tøj tages straks af. Skyl/brus huden med vand.

Alt tilsmudset tøj skal vaskes inden genanvendelse.

VED INDÅNDING: Flyt personen til et sted med frisk luft og sørg for, at veirtrækningen 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/læge.

- 3) I deklarationsfeltet:
- a) Teksten "Desinfektionsmiddel BPR-reg, nr. 798-1-1-x[3]. Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)". b) Oplysning om præparattype: "flydende koncentrat" for dette præparat.
- c) Indholdet af aktivstof i vægtprocent (% w/w) og g/L ved 20 °C
- d) "Indeholder svovlsyre, phosphorsyre, alkoholethoxylater (8EO) C9-11"
- e) Udløbsdatoen skal anføres. Denne dato må højst være 3 år efter produktionsdatoen. Etikettens dato kan udformes som en henvisning
- til en produktionsdato andetsteds på emballagen.
- f) Batchnummer eller betegnelse skal anføres.
- g) Pakningsstørrelse i L.
- h) Godkendelsesindehavers navn og adresse.
- 4) Brugsanvisningen:

"Desinfektion af stalde og dyretransporter: rengør overflader før desinfektion. Lad produktet virke minimum 30 minutter, skyl af i vand. Kun til desinfektion mod bakterier, gær, mykobakterier og virus.

Desinfektion af stald-, hav- og dambrugsudstyr: Rengør udstyr før desinfektion, nedsænk produktet i minimum 30 minutter, skyl af i vand. Kun til desinfektion mod bakterier, gær, mykobakterier og virus. Støvle- og hjulbad: Rengør før desinfektion, lad produktet virke minimum 2 minutter, skyl af i vand. Kun til desinfektion mod

bakterier. Støvlebad skiftes efter behov, dog minimum hver anden dag."

Oplysninger om mikroorganismer, indvirkningstid, 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