

Summary of product characteristics for a biocidal product

Product name: Tork Hand Sanitizing Alcohol-Free Foam

Product type(s): PT01 - Human hygiene (Disinfectants)

Authorisation number: 1013-1

R4BP 3 asset reference number: DK-0025926-0000

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Administrative information

1.1. Trade names of the product

Tork Hand Sanitizing Alcohol-Free Foam

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Essity Hygiene and Health Aktiebolag
	Address	Broplatsen 3 431 31 Mölndal Sweden
Authorisation number	1013-1	
R4BP 3 asset reference number	DK-0025926-0000	
Date of the authorisation	14/12/2020	
Expiry date of the authorisation	07/06/2027	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	SALVECO S.A.S
Address of the manufacturer	Avenue Pierre Mendes-France F-88100 SAINT DIE DES VOSGES France
Location of manufacturing sites	Avenue Pierre Mendes-France F-88100 SAINT DIE DES VOSGES France

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

Active substance	1421 - Lactic acid
Name of the manufacturer	JUNGBUNGZLAUER S.A
Address of the manufacturer	Z.I Portuaire BP 32 67390 Marckolsheim France
Location of manufacturing sites	Z.I Portuaire BP 32 67390 Marckolsheim France

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 (%)
Lactic acid		Active Substance		200-018-0	1,75

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements	Safety data sheet available on request.
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children.

4. Authorised use(s)

4.1 Use description

Use 1 - Hygienic handrub for professional and non-professional users – 30 months

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Hygienic handrub. Ready-to-use disinfectant for hands with a bactericidal, yeasticidal and virudical (only against enveloped viruses) efficacy in domestic, medical, institutional and industrial area.
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: Scientific name: Yeasts Common name: Yeasts Development stage: Scientific name: Enveloped viruses Common name: Enveloped viruses Development stage:
Field(s) of use	Indoor Outdoor
Application method(s)	Method: Manual application: spreading and foam application Detailed description: Place 3ml on clean hands and wrists. Rub for at least 30 seconds. Do not rinse.
Application rate(s) and frequencies	Application Rate: 3mL Dilution (%): Ready-to-use Number and timing of application: Apply once. Repeat if renewed hand disinfection is needed.
Category(ies) of users	Industrial Professional General public (non-professional)
Pack sizes and packaging material	Bottle, Plastic: PET, PE, PP , 0.01 -5L (consumers and professional users) Pouches, Plastic: LDPE, LLDPE , 0.01-5L (consumers and professional users) Drum, Plastic: HDPE , 10-210L (professional, industrial) Description (not mentioned on the label): All the used packaging are secure, closed, tight, strong and durable. Packaging can be refilled only with product foreseen for that purpose.

4.1.1 Use-specific instructions for use

Section 5.1. (Directions for use)

4.1.2 Use-specific risk mitigation measures

Section 5.2. (Directions for use)

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

Section 5.3. (Directions for use)

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

Section 5.4. (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

Section 5.5. (Directions for use)

5. General directions for use

5.1. Instructions for use

Place 3 ml on clean hands and wrists. Rub for at least 30 seconds. Do not rinse. Apply once, repeat if renewed hand disinfection is needed.

5.2. Risk mitigation measures

Not applicable.

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

No direct or indirect adverse effects are known.
First aid instructions:
If swallowed: immediately call a POISON CENTER or doctor/physician.
In case of contact with eyes, remove contact lenses if present and rinse the eye slowly and gently with clean water.

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

Dispose of contents/container in accordance with national regulation.

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

Products can be stored at room temperature up to 30 months.
Protect from cold and heat.

6. Other information

(*) Not surgical handrub.

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 [1].

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.
Nedstående 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. Op-lys-ninger i citationstegn skal angives ordret:

1) I hovedfeltet:
"Hånddesinfektion

Må kun anvendes som hånddesinfektion mod bakterier, gær og kappebærende virus. Må anvendes industrielt, professionelt og af ikke-professionelle"

2) I advarselsfeltet:
"FORSIGTIG [2]

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

Må kun anvendes som hånddesinfektion mod bakterier, svampe og kappebærende virus. Må anvendes industrielt, professionelt og af ikke-professionelle.

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

**Må ikke tømmes i kloak afløb.
Opbevares utilgængeligt for børn.
Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.**

Levnedsmidler og foderstoffer må ikke forurenes.

Evt. oplysninger om førstehjælp.

3) I deklaraionsfeltet:

a) Teksten "Hånddesinfektion, BPR-reg. nr. 1013-2. Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)".

b) Oplysning om præparattype: "Væske" for dette præparat.

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

e) Udløbsdatoen skal anføres. Denne dato må højst være 30 måneder efter produktionsdatoen. Etikettens dato kan udformes som

en hen-visning til en produktionsdato andetsteds på emballagen. Opbevares beskyttet mod kulde og varme.

f) Batchnummer eller – betegnelse skal anføres.

g) Pakningsstørrelse i L.

h) 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."

Ovenstående sætning er Miljøstyrelsens vejledning om affaldshåndtering af dette produkt. Følg altid kommunens affaldsregulativ og forhør dig hos kommunen, hvis du er i tvivl.