

Summary of product characteristics for a biocidal product family

Family name: SANYTOL FRESH

Product type(s): PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

PT04 - Food and feed area (Disinfectants)

Authorisation number: 860-1

R4BP 3 asset reference number: DK-0023743-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

SANYTOL FRESH

1.2. Product type(s)

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
PT04 - Food and feed area (Disinfectants)

1.3. Authorisation holder

Name and address of the
authorisation holder

Name	GRUPO AC MARCA S.L.
Address	Avda. Carrilet, 293-297 08907 L'Hospitalet de Llobregat Spain

Authorisation number

860-1

R4BP 3 asset reference
number

DK-0023743-0000

Date of the authorisation

29/04/2020

Expiry date of the
authorisation

20/04/2030

1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer	GRUPO AC MARCA S.L.
Address of the manufacturer	Avda. Carrilet, 293-297 08907 08907 L'Hospitalet de Llobregat, Barcelona Spain
Location of manufacturing sites	Polígono Industrial Can Serra III, Parcela I 08791 Sant Llorenç d'Hortons, Barcelona Spain
	Polígono Industrial Can Barri. C/ Esqueis S/N 08415 Bigues i Riells, Barcelona Spain
	Prismasy 124 28201 Cesky Brod Czech Republic

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

Active substance	1315 - Hydrogen peroxide
Name of the manufacturer	PeroxyChem Spain s.l.u
Address of the manufacturer	c/ Afueras s/n 50784 La Zaida, Zaragoza Spain
Location of manufacturing sites	c/ Afueras s/n 50784 La Zaida, Zaragoza Spain

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 (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5 - 1,5
Ethanol	Ethanol		64-17-5	200-578-6	2,88 - 3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,275 - 0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48 - 0,5
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,42 - 0,96

1-Deoxi-1-(metil-(C8-10-
(numeración par)-
alcanoil)amino)-D-Glucitol

1-Deoxi-1-(metil-(C8-10-
(numeración par)-
alcanoil)amino)-D-Glucitol

940-284-1

0 - 0,5

2.2. Type(s) of formulation

AL (any other liquid) ready-to-use

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

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 1

1.2. Suffix to the authorisation number

1-1

1.3 Product type(s)

PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)

PT04 - Food and feed area (Disinfectants)

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 (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5 - 1,5
Ethanol	Ethanol		64-17-5	200-578-6	3 - 3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49 - 0,49

1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide	2605-79-0	220-020-5	0,48 - 0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides		483-960-7	0,67 - 0,96
1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol		940-284-1	0 - 0

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

Formulation(s)

AL (any other liquid) ready-to-use

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Causes serious eye irritation.

Precautionary statements

If medical advice is needed, have product container or label at hand.

Keep out of reach of children.

Read carefully and follow all instructions.

Wash hands thoroughly after handling.

Wear eye protection.

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

If eye irritation persists: Get medical advice.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Hard surface disinfection

Product type

PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)

PT04 - Food and feed area (Disinfectants)

Where relevant, an exact description of the authorised use	Hard surface
Target organism(s) (including development stage)	<p>Scientific name: Common name: Bacteria Development stage:</p> <p>Scientific name: Common name: Yeasts Development stage:</p> <p>Scientific name: Common name: Fungi Development stage:</p>
Field(s) of use	<p>Indoor</p> <p>Indoor use. To be used in Commercial premises (Food, Industrial and Institutional areas), Households / private areas (Domestic areas)</p>
Application method(s)	<p>Manual spraying - -</p> <p>Manual spraying and wiping - -</p>
Application rate(s) and frequencies	<p>-- 0 - Ready to use Contact time: Bacteria: 5 minutes Fungi and yeasts: 15 min Temperature: 20°C</p> <p>-- 0 - Ready to use Contact time: Bacteria: 5 minutes Fungi and yeasts: 15 min Temperature: 20°C</p>
Category(ies) of users	<p>Professional</p> <p>General public (non-professional)</p>
Pack sizes and packaging material	<p>HDPE bottle with trigger TS3 SO SPRAY: 500, 600, 700, 750, 900, 1000 mL HDPE bottle with trigger TS3 SO FOAM V20: 500, 600, 700, 750, 900, 1000 mL</p>

4.1.1 Use-specific instructions for use

- Manual spray and wiping on hard surface: Apply uniformly on the surface to be treated in sufficient quantity so that surfaces remain wet during at least for 5 minutes for bactericidal efficacy and for 15 minutes for yeasticidal and fungicidal efficacy, wipe the surface with a wet and clean cloth. Let the surface dry.
- Manual spray on hard surface: Apply uniformly on the surface to be treated in sufficient quantity so that surfaces remain wet during at least for 5 minutes for bactericidal efficacy and for 15 minutes for yeasticidal and fungicidal efficacy. Let the surface dry.

4.1.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

4.2 Use description

Use 2 - Soft surface disinfection

Product type

PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
PT04 - Food and feed area (Disinfectants)

Where relevant, an exact description of the authorised use

Soft surface

Target organism(s) (including development stage)

Scientific name:
Common name: Bacteria
Development stage:

Scientific name:
Common name: Yeasts
Development stage:

Scientific name:
Common name: Fungi
Development stage:

Field(s) of use	Indoor Indoor use. To be used in commercial premises (Food, Industrial and Institutional areas), Households / private areas (Domestic areas)
Application method(s)	Manual spraying - -
Application rate(s) and frequencies	- - 0 - Ready to use Contact time: Bacteria, fungi and yeasts: 45 minutes Temperature: 20°C
Category(ies) of users	Professional General public (non-professional)
Pack sizes and packaging material	HDPE bottle with trigger TS3 SO SPRAY: 500, 600, 700, 750, 900, 1000 mL HDPE bottle with trigger TS3 SO FOAM V20: 500, 600, 700, 750, 900, 1000 mL

4.2.1 Use-specific instructions for use

- Manual spray on soft surfaces: Apply uniformly on the surface to be treated in sufficient quantity so that surfaces remain wet during at least for 45 minutes. Let the surface dry.

4.2.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

5. General directions for use of the meta SPC

5.1. Instructions for use

- Always read the label or leaflet before use and respect all the instructions provided.
- For professional users:**
- Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved. Inform the authorization holder if the treatment is ineffective.

5.2. Risk mitigation measures

For professional users:

During the spray application, facial exposure to generated aerosols has to be limited by the use of PPE and application of technical and organisational RMM such as:

- o Minimisation of splashes and spills;
 - o Downward spray application in order to avoid any facial exposure;
 - o Minimise number of staff exposed.
- PPE for the spraying phase are as following:
- o Eye protection.

For non-professional users:

The spray application should be done downward in order to avoid any facial exposure.

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

- Inhalation (spray mist): Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.
- Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur.
- Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.
- Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested.
- In case of impaired consciousness place in recovery position and seek medical advice immediately. Do not give fluids or induce vomiting.
- Keep the container or label available.

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

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

Shelf-life two years.
Protect from frost and light.

6. Other information

The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA).
The studies of long term storage should be provided within two years.

Bilag 1

Oplysninger til etiket og brugsanvisning for Sanytol Fresh, Meta-SPC 1, BPR-reg. nr. 860-1-1-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.
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. Oplysninger i citationstegn skal angives ordret:

1) I hovedfeltet:
"Desinfektionsmiddel

Må kun anvendes som desinfektionsmiddel mod bakterier, gær og svampe. Må kun anvendes indendørs på hårde overflader ved manuel sprøjtning og aftørring, samt på bløde overflader ved manuel sprøjtning."

2) I advarselsfeltet:
"ADVARSEL

Forårsager alvorlig øjenirritation (H319).

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

Læs etiketten før brug.

Vask hænder grundigt efter brug.

Specifikt for professionelle: Bær øjenbeskyttelse.

For professionelle og ikke-professionelle: Spray er kun tilladt i nedadgående retning. Undgå kontakt med øjne.

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

Må kun anvendes som desinfektionsmiddel mod bakterier, gær og svampe. Må kun anvendes indendørs på hårde overflader ved manuel sprøjtning og aftørring samt på bløde overflader ved manuel sprøjtning.

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

Opbevares utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.

Levnedsmidler og foderstoffer må ikke forurennes."

Farepiktogrammet GHS07.

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 vedvarende øjenirritation: Søg lægehjælp.

3) I deklarationsfeltet:

a) Teksten "Desinfektionsmiddel BPR-reg. nr. 860-1-1-x. 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.

d) Sætningen: "Indeholder: L-(+)-lactic acid; 1-Decanamine, N,N-dimethyl, N-oxide og D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides".

e) Udløbsdatoen skal anføres. Denne dato må højst være 2 år efter produktionsdatoen. Etikettens dato kan udformes som en hen-visning til en produktionsdato andetsteds på emballagen.

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/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."

[1] "x" skal erstattes med et tal som angivet i godkendelsesbrevets bilag 4.

[1] Europa-Parlamentets og Rådets forordning (EF) Nr. 1272/2008 af 16. december 2008 om klassificering, mærkning og emballering af stoffer og blandinger og om ændring og ophævelse af direktiv 67/548/EØF og 1999/45/EF og om ændring af forordning (EF) nr. 1907/2006

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)

SANYTOL DESINFICERENDE
UNIVERSALRENGØRING FRESH

Market area: DK

Authorisation number

DK-0023743-0001 1-1

(R4BP 3 asset reference number - National
Authorisation)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,96
1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol			940-284-1	0

Trade name(s)

Sanytol Desinficerende universalrengøring
GRAPEFRUGT FRESH

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0023743-0002 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,96

1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	940-284-1	0
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Trade name(s)

Sanytol Desinficerende universalrengøring
FYRRETRÆ FRESH

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0023743-0003 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,96
1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol			940-284-1	0

Trade name(s)

SANYTOL DESINFECTANT MULTI
FORMÁL NEUTRAL FRESH

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0023743-0004 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,96
1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol			940-284-1	0

Trade name(s)

Sanytol Desinficerende universalrengøring
Æble FRESH

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0023743-0005 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,96

1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	940-284-1	0
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Trade name(s)

Sanytol Desinficerende universalrengøring
Frisk Luft FRESH

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0023743-0006 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,96
1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol			940-284-1	0

Trade name(s)

SANYTOL DESINFICERENDE
BADEVÆRELSE FRESH

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0023743-0007 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,96
1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol			940-284-1	0

Trade name(s)

SANYTOL Desinficerende lugt FRESH

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0023743-0008 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,96

1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	940-284-1	0
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Trade name(s)

Sanytol Desinficerende Lugtfjerner til Tekstiler FRESH

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0023743-0009 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,96
1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol			940-284-1	0

Trade name(s)

SANYTOL Desinficerende tekstilneutral FRESH

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0023743-0010 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,96
1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol			940-284-1	0

Trade name(s)

Sanytol Desinficerende universalrengøring
FRESH PROFESSIONEL

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0023743-0011 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,96

1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	940-284-1	0
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Trade name(s)

Sanytol Desinficerende badeværelse FRESH PROFESSIONEL

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0023743-0012 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,96
1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol			940-284-1	0

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 2

1.2. Suffix to the authorisation number

1-2

1.3 Product type(s)

PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)

PT04 - Food and feed area (Disinfectants)

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 (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5 - 1,5
Ethanol	Ethanol		64-17-5	200-578-6	2,88 - 2,88
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,275 - 0,275
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,5 - 0,5
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,42 - 0,6
1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol			940-284-1	0,5 - 0,5

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

Formulation(s)

AL (any other liquid) ready-to-use

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Causes serious eye irritation.

Precautionary statements

If medical advice is needed, have product container or label at hand.

Keep out of reach of children.

Read carefully and follow all instructions.

Wash hands thoroughly after handling.

Wear eye protection.

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

If eye irritation persists: Get medical advice.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Hard surface disinfection

Product type

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

PT04 - Food and feed area (Disinfectants)

Where relevant, an exact description of the authorised use

Hard surface

Target organism(s) (including development stage)

Scientific name:
Common name: Bacteria
Development stage:

Scientific name:
Common name: Yeasts
Development stage:

Scientific name:
Common name: Fungi
Development stage:

Field(s) of use

Indoor

Indoor use.
To be used in Commercial premises (Food, Industrial and Institutional areas),
Households / private areas (Domestic areas)

Application method(s)

Manual spraying -

-

Manual spraying and wiping -

-

Application rate(s) and frequencies

-- 0 -

Ready to use

Contact time:

	<p>Bacteria: 5 minutes Fungi and yeasts: 15 min Temperature: 20°C</p> <p>-- 0 --</p> <p>Ready to use Contact time: Bacteria: 5 minutes Fungi and yeasts: 15 min Temperature: 20°C</p>
Category(ies) of users	<p>Professional</p> <p>General public (non-professional)</p>
Pack sizes and packaging material	<p>HDPE bottle with trigger TS3 SO SPRAY: 500, 600, 700, 750, 900, 1000 mL HDPE bottle with trigger TS3 SO FOAM V20: 500, 600, 700, 750, 900, 1000 mL</p>

4.1.1 Use-specific instructions for use

- Manual spray and wiping on hard surface: Apply uniformly on the surface to be treated in sufficient quantity so that surfaces remain wet during at least for 5 minutes for bactericidal efficacy and for 15 minutes for yeasticidal and fungicidal efficacy, wipe the surface with a wet and clean cloth. Let the surface dry.
- Manual spray on hard surface: Apply uniformly on the surface to be treated in sufficient quantity so that surfaces remain wet during at least for 5 minutes for bactericidal efficacy and for 15 minutes for yeasticidal and fungicidal efficacy. Let the surface dry.

4.1.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

5. General directions for use of the meta SPC

5.1. Instructions for use

- Always read the label or leaflet before use and respect all the instructions provided.

For professional users:

- Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved. Inform the authorization holder if the treatment is ineffective.

5.2. Risk mitigation measures

For professional users:

During the spray application, facial exposure to generated aerosols has to be limited by the use of PPE and application of technical and organisational RMM such as:

- o Minimisation of splashes and spills;
- o Downward spray application in order to avoid any facial exposure;
- o Minimise number of staff exposed.

- PPE for the spraying phase are as following:

- o Eye protection.

For non-professional users:

The spray application should be done downward in order to avoid any facial exposure.

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

- Inhalation (spray mist): Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.
- Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur.
- Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.
- Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested.
- In case of impaired consciousness place in recovery position and seek medical advice immediately. Do not give fluids or induce vomiting.
- Keep the container or label available.

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

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

Shelf-life two years.
Protect from frost and light.
For meta SPC 2: do not store at temperature above 35°C.

6. Other information

The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA).
- The studies of long term storage should be provided within two years.

Bilag 1

Oplysninger til etiket og brugsanvisning for Sanytol Fresh, Meta-SPC 2, BPR-reg. nr. 860-1-2-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.

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. Oplysninger i citationstegn skal angives ordret:

1) I hovedfeltet:
"Desinfektionsmiddel

Må kun anvendes som desinfektionsmiddel mod bakterier, gær og svampe. Må kun anvendes indendørs på hårde overflader ved manuel sprøjtning og aftørring."

2) I advarselsfeltet:
"ADVARSEL

Forårsager alvorlig øjenirritation (H319).

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

Læs etiketten før brug.

Vask hænder grundigt efter brug.

Specifikt for professionelle: Bær øjenbeskyttelse (P280).

For professionelle og ikke-professionelle: Spray er kun tilladt i nedadgående retning. Undgå kontakt med øjne.

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

Må kun anvendes som desinfektionsmiddel mod bakterier, gær og svampe. Må kun anvendes indendørs på hårde overflader ved manuel sprøjtning og aftørring.

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

Opbevares utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.

Levnedsmidler og foderstoffer må ikke forurennes."

Farepiktogrammet GHS07.

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 vedvarende øjenirritation: Søg lægehjælp.

3) I deklaraionsfeltet:

a) Teksten "Desinfektionsmiddel BPR-reg. nr. 860-1-2-x. 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.

- d) Sætningen: "Indeholder: L-(+)-lactic acid; 1-Decanamine, N,N-dimethyl, N-oxide; D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides og 1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol".
- e) Udløbsdatoen skal anføres. Denne dato må højst være 2 år efter produktionsdatoen. Etikettens dato kan udformes som en hen-visning til en produktionsdato andetsteds på emballagen.
- 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/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."

[1] "x" skal erstattes med et tal som angivet i godkendelsesbrevets bilag 4.

[1] Europa-Parlamentets og Rådets forordning (EF) Nr. 1272/2008 af 16. december 2008 om klassificering, mærkning og emballering af stoffer og blandinger og om ændring og ophævelse af direktiv 67/548/EØF og 1999/45/EF og om ændring af forordning (EF) nr. 1907/2006

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)	SANYTOL DESINFICERENDE KØKKEN FRESH	Market area: DK
Authorisation number	DK-0023743-0013 1-2	
<small>(R4BP 3 asset reference number - National Authorisation)</small>		

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	2,88
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,275
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,5

D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	483-960-7	0,42
1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	940-284-1	0,5

Trade name(s)

SANYTOL DESINFICERENDE
RENGØRINGS MIDDEL 4 AKTIONS
FRESH

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0023743-0014 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	2,88
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,275
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,5
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,42
1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol			940-284-1	0,5

Trade name(s)

Sanytol Desinficerende køkken FRESH
PROFESSIONEL

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0023743-0015 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	2,88
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,275
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,5
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,42
1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol			940-284-1	0,5

Trade name(s)

SANYTOL DESINFICERENDE
RENGØRINGS MIDDEL 4 AKTIONES
FRESH PROFESSIONEL

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0023743-0016 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5

Ethanol	Ethanol	64-17-5	200-578-6	2,88
L-(+)-lactic acid	2- Hydroxy propanoic acid	79-33-4	201-196-2	0,275
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide	2605-79-0	220-020-5	0,5
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides		483-960-7	0,42
1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol		940-284-1	0,5

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 3

1.2. Suffix to the authorisation number

1-3

1.3 Product type(s)

PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)

PT04 - Food and feed area (Disinfectants)

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 (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5 - 1,5

Ethanol	Ethanol	64-17-5	200-578-6	3 - 3
L-(+)-lactic acid	2- Hydroxy propanoic acid	79-33-4	201-196-2	0,49 - 0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide	2605-79-0	220-020-5	0,48 - 0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides		483-960-7	0,67 - 0,96
1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol		940-284-1	0 - 0

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

Formulation(s)

AL (any other liquid) ready-to-use

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Causes serious eye irritation.

Precautionary statements

If medical advice is needed, have product container or label at hand.

Keep out of reach of children.

Read carefully and follow all instructions.

Wash hands thoroughly after handling.

Wear eye protection.

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

If eye irritation persists: Get medical advice.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Hard surface disinfection

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Hard surface
Target organism(s) (including development stage)	Scientific name: Common name: Bacteria Development stage: Scientific name: Common name: Yeasts Development stage: Scientific name: Common name: Fungi Development stage:
Field(s) of use	Indoor Indoor use. To be used in Commercial premises (Food, Industrial and Institutional areas), Households / private areas (Domestic areas)
Application method(s)	Manual pouring and wiping - -
Application rate(s) and frequencies	-- 0 - Ready to use Contact time: Bacteria: 5 minutes Fungi and yeasts: 15 min Temperature: 20°C
Category(ies) of users	Professional General public (non-professional)
Pack sizes and packaging material	HDPE bottle: 750, 1000, 1200, 1500, 2000 mL HDPE can: 5000 mL Multi-layer PET/PE doy pack: 70, 140 mL

4.1.1 Use-specific instructions for use

- Manual pouring and wiping on hard surface: Apply uniformly on the surface to be treated in sufficient quantity so that surfaces remain wet during at least for 5 minutes for bactericidal efficacy and for 15 minutes for yeasticidal and fungicidal efficacy, wipe the surface with a wet and clean cloth. Let the surface dry.

4.1.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

5. General directions for use of the meta SPC

5.1. Instructions for use

Always read the label or leaflet before use and respect all the instructions provided.

For professionals users:

- Refer to hygiene plan in place in order to ensure that necessary efficacy level is achieved. Inform the authorization holder if the treatment is ineffective.

5.2. Risk mitigation measures

-

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

- Inhalation (spray mist): Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.
- Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur.
- Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.
- Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested.

- In case of impaired consciousness place in recovery position and seek medical advice immediately. Do not give fluids or induce vomiting.
- Keep the container or label available.

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

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

Shelf-life two years.
Protect from frost and light.

6. Other information

- The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA).
- The studies of long term storage should be provided within two years.

Bilag 1

Oplysninger til etiket og brugsanvisning for Sanytol Fresh, Meta-SPC 1, BPR-reg. nr. 860-1-3-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.

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. Oplysninger i citationstegn skal angives ordret:

1) I hovedfeltet:
"Desinfektionsmiddel

Må kun anvendes som desinfektionsmiddel mod bakterier, gær og svampe. Må kun anvendes indendørs på hårde overflader ved manuel hældning og aftørring."

2) I advarselsfeltet:
"ADVARSEL

Forårsager alvorlig øjenirritation (H319).

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

Læs etiketten før brug.

Vask hænder grundigt efter brug (P264).

Specifikt for professionelle: Bær øjenbeskyttelse (P280).

Undgå kontakt med øjne.

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

Må kun anvendes som desinfektionsmiddel mod bakterier, gær og svampe.

Må kun anvendes indendørs på hårde overflader ved manuel hældning og aftørring.

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

Opbevares utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.

Levnedsmidler og foderstoffer må ikke forurenes.

Farepiktogrammet GHS07.

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 vedvarende øjenirritation: Søg lægehjælp.

3) I deklarationsfeltet:

a) Teksten "Desinfektionsmiddel BPR-reg. nr. 860-1-3-x. 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

d) Sætningen: "Indeholder: L-(+)-lactic acid; 1-Decanamine, N,N-dimethyl, N-oxide og D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides".

e) Udløbsdatoen skal anføres. Denne dato må højst være 2 år efter produktionsdatoen. Etikettens dato kan udformes som en hen-visning til en produktionsdato andetsteds på emballagen.

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."

Derudover skal mærkningen ske efter retningslinjerne:

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

[1] "x" skal erstattes med et tal som angivet i godkendelsesbrevets bilag 4.

[1] Europa-Parlamentets og Rådets forordning (EF) Nr. 1272/2008 af 16. december 2008 om klassificering, mærkning og emballering af stoffer og blandinger og om ændring og ophævelse af direktiv 67/548/EØF og 1999/45/EF og om ændring af forordning (EF) nr. 1907/2006

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)**SANYTOL RENGØRINGS – OG
DESINFEKTIONSMIDDEL FRESH

Market area: DK

Authorisation number

DK-0023743-0017 1-3

(R4BP 3 asset reference number - National
Authorisation)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,96
1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol			940-284-1	0

Trade name(s)

Sanytol Rengørings – og desinfektionsmiddel GRAPEFRUGT FRESH

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0023743-0018 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,96

1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	940-284-1	0
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Trade name(s)

Sanytol Rengørings – og desinfektionsmiddel CITRON FRESH

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0023743-0019 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,96
1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol			940-284-1	0

Trade name(s)

Sanytol Rengørings – og desinfektionsmiddel FYRRETRÆ FRESH

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0023743-0020 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,96
1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol			940-284-1	0

Trade name(s)

Sanytol Rengørings – og desinfektionsmiddel ocean FRESH

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0023743-0021 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,96

1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	940-284-1	0
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Trade name(s)

SANYTOL
RENGØRINGSDISINFEKTIONS
NÆTTRAL
FRESH

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0023743-0022 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,96
1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol			940-284-1	0

Trade name(s)

Sanytol Rengørings – og
desinfektionsmiddel Æble FRESH

Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0023743-0023 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,96
1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol			940-284-1	0

Trade name(s)

Sanytol Rengørings – og desinfektionsmiddel Frisk Luft FRESH

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

DK-0023743-0024 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,96

1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	940-284-1	0
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Trade name(s)

Sanytol Rengørings – og
desinfektionsmiddel FRESH
PROFESSIONEL

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National
Authorisation)

DK-0023743-0025 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,96
1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol			940-284-1	0

Trade name(s)

Sanytol Rengørings – og
desinfektionsmiddel CITRON FRESH
PROFESSIONEL

Market area: DK

Authorisation number

(R4BP 3 asset reference number - National
Authorisation)

DK-0023743-0026 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active Substance	7722-84-1	231-765-0	1,5
Ethanol	Ethanol		64-17-5	200-578-6	3
L-(+)-lactic acid	2- Hydroxy propanoic acid		79-33-4	201-196-2	0,49
1-Decanamine, N,N-dimethyl, N-oxide	N,N-Dimethyldecylamine N-oxide		2605-79-0	220-020-5	0,48
D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides	D-pentose et D-glucose, oligomeric, C8-10-alkyl glycosides			483-960-7	0,96
1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol	1-Deoxi-1-(metil-(C8-10-(numeración par)-alcanoil)amino)-D-Glucitol			940-284-1	0