



2025/1885

19.9.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/1885

of 11 September 2025

**granting a Union authorisation for the biocidal product family 'BPF Propan-2-ol Dr Deppe' in
accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 44(5), first subparagraph, thereof,

Whereas:

- (1) On 29 June 2016, Laboratorium Dr. Deppe GmbH submitted an application to the European Chemicals Agency ('the Agency') in accordance with Article 43(1) of Regulation (EU) No 528/2012 for Union authorisation of a biocidal product family named 'BPF Propan-2-ol Dr Deppe' of product-type 1, as described in Annex V to that Regulation, providing written confirmation that the competent authority of the Netherlands had agreed to evaluate the application. The application was recorded under case number BC-GH025503-55 in the Register for Biocidal Products.
- (2) 'BPF Propan-2-ol Dr Deppe' contains propan-2-ol as the active substance, included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-type 1.
- (3) On 27 May 2024, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the Agency.
- (4) On 13 December 2024, the Agency submitted to the Commission its opinion ⁽²⁾, the draft summary of the biocidal product characteristics ('SPC') of 'BPF Propan-2-ol Dr Deppe' and the final assessment report on the biocidal product family, in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that 'BPF Propan-2-ol Dr Deppe' is a biocidal product family within the meaning of Article 3(1), point (s), of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that, subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(6) of that Regulation.
- (6) On 8 January 2025, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the biocidal product family 'BPF Propan-2-ol Dr Deppe'.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/528/oj>.

⁽²⁾ Opinion of 28 November 2024 on the Union authorisation of the biocidal product family 'BPF Propan-2-ol Dr Deppe' (ECHA/BPC/454/2024), <https://echa.europa.eu/opinions-on-union-authorisation>.

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0033834-0000 is hereby granted to Laboratorium Dr. Deppe GmbH for the making available on the market and use of the biocidal product family 'BPF Propan-2-ol Dr Deppe' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 9 October 2025 until 30 September 2035.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 11 September 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT FAMILY

BPF Propan-2-ol Dr Deppe

Product type(s)

PT01: Human hygiene

Authorisation number: EU-0033834-0000

R4BP asset number: EU-0033834-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	BPF Propan-2-ol Dr Deppe
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1.2. Product type(s)

Product type(s)	PT01: Human hygiene
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1.3. Authorisation holder

Name and address of the authorisation holder	Name	Laboratorium Dr. Deppe GmbH
	Address	Hooghe Weg 35 47906 Kempen DE
Authorisation number	EU-0033834-0000	
R4BP asset number	EU-0033834-0000	
Date of the authorisation	9 October 2025	
Expiry date of the authorisation	30 September 2035	

1.4. Manufacturer(s) of the product

Name of manufacturer	Laboratorium Dr. Deppe GmbH
Address of manufacturer	Hooghe Weg 35 47906 Kempen Germany
Location of manufacturing sites	Laboratorium Dr. Deppe GmbH site 1 Laboratorium Dr. Deppe GmbH, Hooghe Weg 35 47906 Kempen Germany Laboratorium Dr. Deppe GmbH site 2 Laboratorium Dr. Deppe GmbH, Am Selder 35 47906 Kempen Germany

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

Active substance	Propan-2-ol
Name of manufacturer	Brenntag GmbH
Address of manufacturer	Stinnes-Platz 1 45472 Muelheim an der Ruhr Germany
Location of manufacturing sites	Brenntag GmbH site 1 Shell Nederland Raffinaderij B.V., Vondelingenweg 601, Vondelingenplaat 3196KK Rotterdam Netherlands (the) Brenntag GmbH site 2 Exxon Mobil Chemical Plant, 4999 Scenic Highway LA 70805 Baton Rouge United States (the)

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 (%)
Propan-2-ol		Active substance	67-63-0	200-661-7	63,14-64 % (w/w)

2.2. **Type(s) of formulation**

Formulation type(s)	AL Any other liquid XX: wipes impregnated with liquid, ready-to-use
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PART II

SECOND INFORMATION LEVEL META SPC(S)1. **META SPC 1 ADMINISTRATIVE INFORMATION**1.1. **Meta SPC 1 identifier**

Identifier	Meta SPC: meta SPC 1
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1.2. **Suffix to the authorisation number**

Number	1-1
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1.3. **Product type(s)**

Product type(s)	PT01: Human hygiene
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2. META SPC 1 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active substance	67-63-0	200-661-7	63,14-64 % (w/w)

2.2. Type(s) of formulation of the meta SPC 1

Formulation type(s)	AL Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	<p>H225: Highly flammable liquid and vapour.</p> <p>H319: Causes serious eye irritation.</p> <p>H336: May cause drowsiness or dizziness.</p> <p>EUH066: Repeated exposure may cause skin dryness or cracking.</p>
Precautionary statements	<p>P101: If medical advice is needed, have product container or label at hand.</p> <p>P102: Keep out of reach of children.</p> <p>P103: Read carefully and follow all instructions.</p> <p>P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</p> <p>P233: Keep container tightly closed.</p> <p>P240: Ground and bond container and receiving equipment.</p> <p>P241: Use explosion-proof electrical, ventilating, lighting equipment.</p> <p>P243: Take actions to prevent static discharges.</p> <p>P261: Avoid breathing vapours.</p> <p>P271: Use only outdoors or in a well-ventilated area.</p> <p>P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P312: Call a POISON CENTER / doctor if you feel unwell.</p> <p>P337+P313: If eye irritation persists: Get medical advice.</p> <p>P370+P378: In case of fire: Use CO₂, dry chemical, or foam to extinguish.</p>

	<p>P403+P235: Store in a well-ventilated place. Keep cool.</p> <p>P405: Store locked up.</p> <p>P501: Dispose of contents to conform with local / regional / national / international regulations.</p>
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4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1

Use # 1.1 – Hygienic Handrub, General – BP01

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	n/a
Target organism(s) (including development stage)	<p>Common name: Bacteria</p> <p>Common name: Tuberculosis bacteria</p> <p>Common name: Yeasts</p> <p>Common name: Enveloped viruses</p>
Field(s) of use	<p>Indoor use</p> <p>In hospitals and other areas, if a high level of hand hygiene is necessary, e.g.:</p> <ul style="list-style-type: none"> — Domestic use — Recreational areas
Application method(s)	<p>Method: Handrub (hygienic), liquid dispensing onto hands</p> <p>Detailed description:</p> <p>The product is ready to use (RTU).</p>
Application rate(s) and frequency	<p>Application Rate:</p> <p>Adults and children of 12 years and above: 3 ml. The amount of liquid shall resemble the size of a large-sized coin (The number of pumps with the dosing system equivalent to 3 ml of the product to be specified by the authorisation holder within the product information).</p> <p>Children under 12 years: 1,5 ml (The number of pumps with the dosing system equivalent to 1,5 ml of the product to be specified by the authorisation holder within the product information).</p> <p>RTU</p> <p>Number and timing of application:</p> <p>Frequency:</p> <p>Adults and children of 12 years and above: Up to 10 × per day</p> <p>Children under 12 years: Up to 3 × per day</p>
Category(ies) of users	General public (non-professional)

Pack sizes and packaging material	<ul style="list-style-type: none"> — 1 000 ml bottle – high density polyethylene (HDPE) + polypropylene (PP) screw cap (with and without low density polyethylene (LDPE) nozzle) — 500 ml bottle – HDPE + PP screw cap (with and without LDPE nozzle) — 250 ml bottle – HDPE + PP screw flip top cap — 150 ml bottle – HDPE + PP screw flip top cap — 100 ml bottle – HDPE + PP screw flip top cap <p>Abbreviations: HDPE: high density polyethylene LDPE: low density polyethylene PP: polypropylene</p>
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4.1.1. *Use-specific instructions for use*

The product shall be used on visibly clean hands. If hands are dirty, wash with soap and water, rinse and dry before applying the product.

The product is ready-to-use. The product shall be either applied directly or used in a dispenser or with a pump.

Step 1: Apply the following amount of disinfectant:

- Adults and children of 12 years and above: 3 ml
- Children under 12 years: 1,5 ml

Rub into palm of hand. Rub palm to palm to spread disinfectant over entire hands and fingers.

Step 2: Rub the back of your left hand with the palm of the right hand. Reverse and repeat action.

Step 3: Open fingers and rub the finger webs. Reverse and repeat action.

Step 4: Rub palm to palm with fingers interlocked (5 times).

Step 5: Rub thumb of each hand using a rotating movement.

Step 6: Rub the tips of the fingers against the opposite palm using circular movement. Rub wrist with both hands. Allow hands to dry completely.

Keep wet for 30 seconds against bacteria, yeast, tuberculosis bacteria and enveloped viruses.

Do not rinse.

Repeat if renewed hand disinfection is required.

Adults and children of 12 years and above: up to 10 × per day

Children under 12 years: up to 3 × per day

4.1.2. *Use-specific risk mitigation measures*

Use for children (age > 1 year) only under supervision of an adult.

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 general directions for use of Meta SPC 1.

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

See general directions for use of Meta SPC 1.

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

See general directions for use of Meta SPC 1

4.2. Use description

Table 2

Use #1.2 – Hygienic Handrub, Professional – BP01

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	n/a
Target organism(s) (including development stage)	Common name: Bacteria Common name: Tuberculosis bacteria Common name: Yeasts Common name: Enveloped viruses
Field(s) of use	Indoor use In hospitals and other areas, if a high level of hand hygiene is necessary, e.g.: — Domestic use (home care etc.); — Institutional use (research etc.); — Industrial applications, e.g. food, cosmetic, pharmaceutical industry etc.; — Restaurants and large-scale/canteen kitchens; — Recreational areas.
Application method(s)	Method: Handrub (hygienic), liquid dispensing onto hands Detailed description: The product is ready to use (RTU).
Application rate(s) and frequency	Application Rate: Adult: 3 ml. The amount of liquid shall resemble the size of a large-sized coin (The number of pumps with the dosing system equivalent to 3 ml of the product to be specified by the authorisation holder within the product information). RTU Number and timing of application: Frequency: Adult: Up to 25 × per day
Category(ies) of users	Professional
Pack sizes and packaging material	— 5 000 ml canister - HDPE + HDPE screw cap — 1 000 ml bottle – HDPE + PP screw cap (with and without LDPE nozzle) — 500 ml bottle – HDPE + PP screw cap (with and without LDPE nozzle) — 250 ml bottle – HDPE + PP screw flip top cap — 150 ml bottle – HDPE + PP screw flip top cap — 100 ml bottle – HDPE + PP screw flip top cap

4.2.1. Use-specific instructions for use

The product shall be used on visibly clean hands. If hands are dirty, wash with soap and water, rinse and dry before applying the product.

The product is ready-to-use. The product shall be either applied directly or used in a dispenser or with a pump.

Step 1: Apply the following amount of disinfectant:

— Adult: 3 ml

Rub into palm of hand. Rub palm to palm to spread disinfectant over entire hands and fingers.

Step 2: Rub the back of your left hand with the palm of the right hand. Reverse and repeat action.

Step 3: Open fingers and rub the finger webs. Reverse and repeat action.

Step 4: Rub palm to palm with fingers interlocked (5 times).

Step 5: Rub thumb of each hand using a rotating movement.

Step 6: Rub the tips of the fingers against the opposite palm using circular movement. Rub wrist with both hands. Allow hands to dry completely.

Keep wet for 30 seconds against bacteria, yeast, tuberculosis bacteria and enveloped viruses.

Do not rinse.

Repeat if renewed hand disinfection is required (Adult: Up to 25 × per day).

Make sure that the applied product is completely dried before entering a room or area where people will stay for a longer period of time.

Transferring the content of larger packages to e.g. dispenser vessels is possible as far as hygienic requirements for the ambient conditions and for the materials used are met and contamination of the product can be safely excluded.

The canister must be equipped with canister pump dispenser or canister valve. The smaller vessel shall be fitted with a funnel.

All materials must be fully compatible with the product. The dispenser or container, which is refilled, must have the following minimum labelling information:

- The authorisation number
- The trade name of the biocidal product
- The identity and content of each active ingredient
- The instructions for use, including the incorporation time required for the biocidal action
- The information according to CLP

4.2.2. *Use-specific risk mitigation measures*

See general directions for use of Meta SPC1.

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 general directions for use of Meta SPC 1.

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

See general directions for use of Meta SPC 1.

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

See general directions for use of Meta SPC 1.

4.3. Use description

Table 3

Use #1.3 – Surgical Handrub – BP01

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	n/a
Target organism(s) (including development stage)	Common name: Bacteria Common name: Tuberculosis bacteria Common name: Yeasts Common name: Enveloped viruses
Field(s) of use	Indoor use Surgical handrub
Application method(s)	Method: Handrub (surgical), liquid dispensing onto hands and lower arms Detailed description: The product is ready to use (RTU).
Application rate(s) and frequency	Application Rate: 6-12 ml for 90 seconds contact time RTU Number and timing of application: Frequency: Up to 4 × per day.
Category(ies) of users	Professional
Pack sizes and packaging material	— 5 000 ml canister – HDPE + HDPE screw cap — 1 000 ml bottle – HDPE + PP screw cap (with and without LDPE nozzle) — 500 ml bottle – HDPE + PP screw cap (with and without LDPE nozzle) — 250 ml bottle – HDPE + PP screw flip top cap — 150 ml bottle – HDPE + PP screw flip top cap — 100 ml bottle – HDPE + PP screw flip top cap

4.3.1. Use-specific instructions for use

The product shall be used on visibly clean hands and lower arms. If hands are dirty, wash with soap and water, rinse and dry before applying the product.

Rub undiluted solution on skin to keep hands and lower arms moist for 90 seconds.

Use sufficient product to ensure complete coverage during contact time. This may vary with hand size and skin condition.

Approximately 6-12 ml are needed for 90 seconds contact time.

Refilling/decanting of the product shall only be done under aseptic conditions.

The canister must be equipped with canister pump dispenser or canister valve.

The smaller vessel shall be fitted with a funnel.

All materials must be fully compatible with the product.

The dispenser or container, which is refilled, must have the following minimum labelling information:

- The authorisation number
- The trade name of the biocidal product

- The identity and content of each active ingredient
- The instructions for use, including the incorporation time required for the biocidal action
- The information according to CLP

4.3.2. *Use-specific risk mitigation measures*

See general directions for use of Meta SPC 1.

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*

See general directions for use of Meta SPC 1.

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

See general directions for use of Meta SPC 1.

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

See general directions for use of Meta SPC 1.

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 1

5.1. **Instructions for use**

See use-specific instructions for each use.

Comply with the instructions for use.

5.2. **Risk mitigation measures**

All handling shall only take place in well-ventilated areas.

In case of skin dryness, use appropriate skin care lotion.

Avoid contact with eyes.

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

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

In case of fire: Use CO₂, dry chemical, or foam to extinguish.

Dispose of contents/container according to local / regional / national / international regulations.

First aid:

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.

IF ON SKIN: If irritation occurs wash with water and seek medical advice. In cases of unintentional skin exposure: wash with water.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

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

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements.

Waste disposal code: 070604

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

Keep out of reach of children and non-target animals/pets.

Store in the dark. Keep cool. Do not store at temperatures exceeding 35 °C.

Shelf life: 3 years

6. OTHER INFORMATION

Please be aware of the European reference value of 129,2 mg/m³ for the active substance propan-2-ol (CAS No: 67-63-0) which was used for the risk assessment of the biocidal product family.

Professionals (including industrial, professionals) mean trained professional if this is required by national legislation.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

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

Trade name(s)			OP Sept Color	Market area: EU		
			Op Sept Blau	Market area: EU		
			Teva Sept Skin poly-alkoholos bőrfertőtlenítő (színezett)	Market area: EU		
Authorisation number			EU-0033834-0001 1-1			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
Propan-2-ol		Active substance	67-63-0	200-661-7	63,14 % (w/w)	

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

Trade name(s)			OP Sept residue-free	Market area: EU		
			Curacid HD-sept	Market area: EU		
			Manorapid pure	Market area: EU		
			Op Sept pur	Market area: EU		
			Op Sept pure	Market area: EU		
Authorisation number			EU-0033834-0002 1-1			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
Propan-2-ol		Active substance	67-63-0	200-661-7	63,14 % (w/w)	

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

Trade name(s)	OP Sept Classic	Market area: EU
	Camed HD-Plus	Market area: EU
	Curacid Poly	Market area: EU
	Dezodent HW	Market area: EU
	Dr. Desi Händedesinfektion	Market area: EU
	Kühn Händedesinfektion	Market area: EU
	Kühn Händedesinfektion	Market area: EU
	Maimed Clean	Market area: EU
	Manorapid Basic	Market area: EU
	Manorapid r.f.u.	Market area: EU
	Op Derm	Market area: EU
	Op Derm Medical	Market area: EU
	Op Sept	Market area: EU
	OPSept	Market area: EU
	OP-Sept	Market area: EU
	Septomed	Market area: EU
	Teva Sept Hand	Market area: EU
	Teva Sept Hand	Market area: EU
	Teva Sept Skin poly-alkoholos bőrfertőtlenítő és sebészi bemosakodó (színezetlen)	Market area: EU
	Alcoman	Market area: EU
	Alcoman +	Market area: EU
	Alcoman Optima	Market area: EU

			Alcoman Plus	Market area: EU		
			Hand Antiseptic	Market area: EU		
			Hand Disinfection	Market area: EU		
			Hände Antiseptikum	Market area: EU		
			Händedesin-fektion	Market area: EU		
			MyClean IP-Sept	Market area: EU		
			MyClean OP-Sept	Market area: EU		
			Sicu Sept	Market area: EU		
			Actoderm	Market area: EU		
			OP Sept perfume-free	Market area: EU		
			OpSeptClassic - parfümfrei	Market area: EU		
Authorisation number			EU-0033834-0003 1-1			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
Propan-2-ol		Active substance	67-63-0	200-661-7	63,14 % (w/w)	

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	Meta SPC: meta SPC 2
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1.2. Suffix to the authorisation number

Number	1-2
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1.3. Product type(s)

Product type(s)	PT01: Human hygiene
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2. META SPC 2 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active substance	67-63-0	200-661-7	63,14-64 % (w/w)

2.2. Type(s) of formulation of the meta SPC 2

Formulation type(s)	XX: wipes impregnated with liquid, ready-to-use
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	<p>H225: Highly flammable liquid and vapour.</p> <p>H319: Causes serious eye irritation.</p> <p>H336: May cause drowsiness or dizziness.</p> <p>EUH066: Repeated exposure may cause skin dryness or cracking.</p>
Precautionary statements	<p>P101: If medical advice is needed, have product container or label at hand.</p> <p>P102: Keep out of reach of children.</p> <p>P103: Read carefully and follow all instructions.</p> <p>P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</p> <p>P233: Keep container tightly closed.</p> <p>P240: Ground and bond container and receiving equipment.</p> <p>P241: Use explosion-proof electrical, ventilating, lighting equipment.</p> <p>P243: Take actions to prevent static discharges.</p> <p>P261: Avoid breathing vapours.</p> <p>P271: Use only outdoors or in a well-ventilated area.</p> <p>P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P312: Call a POISON CENTER / doctor if you feel unwell.</p> <p>P337+P313: If eye irritation persists: Get medical advice.</p>

	<p>P370+P378: In case of fire: Use CO₂, dry chemical, or foam to extinguish.</p> <p>P403+P235: Store in a well-ventilated place. Keep cool.</p> <p>P405: Store locked up.</p> <p>P501: Dispose of contents to conform with local / regional / national / international regulations.</p>
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4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1

Use #2.1 – Hygienic Handrub, General – BP02

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	n/a
Target organism(s) (including development stage)	<p>Common name: Bacteria</p> <p>Common name: Tuberculosis bacteria</p> <p>Common name: Yeasts</p> <p>Common name: Enveloped viruses</p>
Field(s) of use	<p>Indoor use</p> <p>In hospitals and other areas, if a high level of hand hygiene is necessary, e.g.:</p> <ul style="list-style-type: none"> — Domestic use (home care etc.); — Recreational areas.
Application method(s)	<p>Method: Handrub (hygienic), Wiping</p> <p>Detailed description:</p> <p>Ready to use (RTU) wipes.</p>
Application rate(s) and frequency	<p>Application Rate:</p> <p>Use one wipe to disinfect hands.</p> <p>RTU wipes</p> <p>Number and timing of application:</p> <p>Frequency: Up to 9 wipes per day.</p>
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	<p>Small wipes:</p> <p>Pack sizes: 6 / 12 / 15 / 30 / 48 / 60 / 72 / or 84 wipes per package</p> <p>Total volume of biocide in package: 51,38 / 102,75 / 128,44 / 256,88 / 411,01 / 513,76 / 616,51 / or 719,26 ml</p> <p>Package material: Polyethylene terephthalate/aluminium/low density polyethylene (PET/Alu/LDPE) laminated foil</p> <p>Wipe material: 100 % Lyocell (white fabric, a fiber regenerated from 100 % wood cellulose)</p> <p>Wipe size: 20 × 15 cm</p> <p>Wipe weight: 1,5 g (per wipe)</p> <p>Impregnation liquid weight: 7,5 g (per wipe)</p>

	<p>Large wipes: Pack sizes: 30 / 42 / 60 / 80 or 84 wipes per package Total volume of biocide in package: 513,76 / 719,26 / 1 027,51 / 1 370,02 or 1 438,52 ml Package material: PET/Alu/LDPE laminated foil Wipe material: 100 % Lyocell (white fabric, a fiber regenerated from 100 % wood cellulose) Wipe size: 20 × 30 cm Wipe weight: 3 g (per wipe) Impregnation liquid weight: 15 g (per wipe)</p>
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4.1.1. Use-specific instructions for use

See general directions for use of Meta SPC 2.

4.1.2. Use-specific risk mitigation measures

Use for children (age > 1 year) only under supervision of an adult.

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 general direction for use of Meta SPC 2.

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

See general directions for use of Meta SPC 2.

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

See general directions for use of Meta SPC 2.

4.2. Use description

Table 2

Use #2.2 – Hygienic Handrub, Professional – BP02

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	n/a
Target organism(s) (including development stage)	<p>Common name: Bacteria</p> <p>Common name: Tuberculosis bacteria</p> <p>Common name: Yeasts</p> <p>Common name: Enveloped viruses</p>
Field(s) of use	<p>Indoor use</p> <p>In hospitals and other areas, if a high level of hand hygiene is necessary, e.g.:</p> <ul style="list-style-type: none"> — Domestic use (home care etc.); — Institutional use (research etc.); — Industrial applications, e.g. food, cosmetic, pharmaceutical industry etc.; — Restaurants and large-scale/canteen kitchens; — Recreational areas.
Application method(s)	<p>Method: Handrub (hygienic), Wiping</p> <p>Detailed description:</p> <p>Ready to use (RTU) wipes.</p>

Application rate(s) and frequency	<p>Application Rate: Use one wipe to disinfect hands. RTU wipes</p> <p>Number and timing of application: Frequency: Typically 25 applications per day</p>
Category(ies) of users	Professional
Pack sizes and packaging material	<p>Small wipes: Pack sizes: 6 / 12 / 15 / 30 / 48 / 60 / 72 / or 84 wipes per package Total volume of biocide in package: 51,38 / 102,75 / 128,44 / 256,88 / 411,01 / 513,76 / 616,51 / or 719,26 ml Package material: PET/Alu/LDPE laminated foil Wipe material: 100 % Lyocell (white fabric, a fiber regenerated from 100 % wood cellulose) Wipe size: 20 × 15 cm Wipe weight: 1,5 g (per wipe) Impregnation liquid weight: 7,5 g (per wipe)</p> <p>Large wipes: Pack sizes: 30 / 42 / 60 / 80 / or 84 wipes per package Total volume of biocide in package: 513,76 / 719,26 / 1 027,51 / 1 370,02 / or 1 438,52 ml Package material: Polyethylene terephthalate (PET)/Alu/LDPE laminated foil Wipe material: 100 % Lyocell (white fabric, a fiber regenerated from 100% wood cellulose) Wipe size: 20 × 30 cm Wipe weight: 3 g (per wipe) Impregnation liquid weight: 15 g (per wipe)</p>

4.2.1. *Use-specific instructions for use*

Make sure that the applied product is completely dried before entering a room or area where people will stay for a longer period of time.

See the general use instructions of Meta SPC 2.

4.2.2. *Use-specific risk mitigation measures*

See general directions for use of Meta SPC 2.

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 general directions for use of Meta SPC 2.

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

See general directions for use of Meta SPC 2.

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

See general directions for use of Meta SPC 2.

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 2

5.1. Instructions for use

Comply with the instructions for use.

The product shall be used on visibly clean hands. If hands are dirty, wash with soap and water, rinse and dry before applying the product.

The wipes are ready-to-use. Only wet wipes are efficacious, dried wipes are to be discarded. Rub hands evenly with one wipe to keep hands moist for 30 seconds.

Please ensure that also all spaces between the fingers, the fingernail angles and skin folds are moistened completely and over the entire exposure time.

5.2. Risk mitigation measures

All handling shall only take place in well-ventilated areas.

Used wipes must be disposed in a closed container.

In case of skin dryness, use appropriate skin care lotion.

Avoid contact with eyes.

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

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

In case of fire: Use CO₂, dry chemical, or foam to extinguish.

Dispose of contents/container according to local / regional / national / international regulations.

Keep out of reach of children and non-target animals/pets.

First aid:

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

IF SWALLOWED: Rinse mouth. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

IF ON SKIN: If irritation occurs wash with water and seek medical advice. In cases of unintentional skin exposure: wash with water.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

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

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements

Waste disposal code: 070604

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

Keep out of reach of children and non-target animals/pets.

Store in the dark. Keep cool. Do not store at temperatures exceeding 40 °C.

Shelf life: 1 year

6. OTHER INFORMATION

Please be aware of the European reference value of 129,2 mg/m³ for the active substance propan-2-ol (CAS No: 67-63-0) which was used for the risk assessment of the biocidal product family.

Professionals (including industrial, professionals) mean trained professional if this is required by national legislation.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

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

Trade name(s)	OPSept Medical	Market area: EU			
	Alcohol Wipes	Market area: EU			
	Alcoman Tücher	Market area: EU			
	Alcoman Wipes	Market area: EU			
	Chucky Wipes	Market area: EU			
	Deppe Wipes	Market area: EU			
	Desi Wipes	Market area: EU			
	IP-Wipes	Market area: EU			
	Op Sept Medical	Market area: EU			
	Op Sept Wipes	Market area: EU			
	OPSept medical perfume-free	Market area: EU			
Authorisation number		EU-0033834-0004 1-2			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active substance	67-63-0	200-661-7	63,14 % (w/w)

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 3 identifier

Identifier	Meta SPC: meta SPC 3
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1.2. Suffix to the authorisation number

Number	1-3
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1.3. **Product type(s)**

Product type(s)	PT01: Human hygiene
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2. META SPC 3 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 3**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active substance	67-63-0	200-661-7	64-64 % (w/w)

2.2. **Type(s) of formulation of the meta SPC 3**

Formulation type(s)	AL Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	<p>H225: Highly flammable liquid and vapour.</p> <p>H319: Causes serious eye irritation.</p> <p>H336: May cause drowsiness or dizziness.</p> <p>EUH066: Repeated exposure may cause skin dryness or cracking.</p>
Precautionary statements	<p>P101: If medical advice is needed, have product container or label at hand.</p> <p>P102: Keep out of reach of children.</p> <p>P103: Read carefully and follow all instructions.</p> <p>P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</p> <p>P233: Keep container tightly closed.</p> <p>P240: Ground and bond container and receiving equipment.</p> <p>P241: Use explosion-proof electrical, ventilating, lighting equipment.</p> <p>P243: Take actions to prevent static discharges.</p> <p>P261: Avoid breathing vapours.</p> <p>P271: Use only outdoors or in a well-ventilated area.</p> <p>P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p>

	<p>P312: Call a POISON CENTER / doctor if you feel unwell.</p> <p>P337+P313: If eye irritation persists: Get medical POISON CENTER / doctor.</p> <p>P370+P378: In case of fire: Use CO₂, dry chemical, or foam to extinguish.</p> <p>P403+P235: Store in a well-ventilated place. Keep cool.</p> <p>P405: Store locked up.</p> <p>P501: Dispose of contents to conform with local / regional / national / international regulations.</p>
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4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1

Use #3.1 – Hygienic Handrub, General – BP03

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	n/a
Target organism(s) (including development stage)	<p>Common name: Bacteria</p> <p>Common name: Yeasts</p> <p>Common name: Enveloped viruses</p>
Field(s) of use	<p>Indoor use</p> <p>In hospitals and other areas, if a high level of hand hygiene is necessary, e.g.:</p> <ul style="list-style-type: none"> — Domestic use (home care etc.); — Recreational areas.
Application method(s)	<p>Method: Handrub (hygienic), gel dispensing onto hands</p> <p>Detailed description:</p> <p>The product is ready to use (RTU).</p>
Application rate(s) and frequency	<p>Application Rate:</p> <p>Adults and children of 12 years and above: 3 ml. The amount of gel shall resemble the size of a large-sized coin (The number of pumps with the dosing system equivalent to 3 ml of the product to be specified by the authorisation holder within the product information).</p> <p>Children under 12 years: 1,5 ml (The number of pumps with the dosing system equivalent to 1,5 ml of the product to be specified by the authorisation holder within the product information).</p> <p>RTU</p> <p>Number and timing of application:</p> <p>Frequency:</p> <p>Adults and children of 12 years and above: Up to 10 × per day</p> <p>Children under 12 years: Up to 3 × per day</p>
Category(ies) of users	General public (non-professional)

Pack sizes and packaging material	<ul style="list-style-type: none"> — 1 000 ml bottle – HDPE + PP screw cap (with and without LDPE nozzle) — 1 000 ml bottle – HDPE + PP/PE dosing cap — 500 ml bottle – HDPE + PP screw cap (with and without LDPE nozzle) — 150 ml bottle – HDPE + PP screw flip top cap — 100 ml bottle – HDPE+ PP screw flip top cap
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4.1.1. *Use-specific instructions for use*

The product shall be used on visibly clean hands. If hands are dirty, wash with soap and water, rinse and dry before applying the product.

The product is ready-to-use.

Step 1: Apply the following amount of disinfectant:

- Adult and children of 12 years and above: 3 ml
- Child under 12 years: 1,5 ml

Rub into palm of hand. Rub palm to palm to spread disinfectant over entire hands and fingers.

Step 2: Rub the back of your left hand with the palm of the right hand. Reverse and repeat action.

Step 3: Open fingers and rub the finger webs. Reverse and repeat action.

Step 4: Rub palm to palm with fingers interlocked (5 times).

Step 5: Rub thumb of each hand using a rotating movement.

Step 6: Rub the tips of the fingers against the opposite palm using circular movement. Rub wrist with both hands. Allow hands to dry completely.

Keep wet for 30 sec against bacteria, yeast and enveloped viruses.

Do not rinse.

Repeat if renewed hand disinfection is required.

Adults and children of 12 years and above: up to 10 × per day

Children under 12 years: up to 3 × per day

4.1.2. *Use-specific risk mitigation measures*

Use for children (age > 1 year) only under supervision of an adult.

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 general directions for use of Meta SPC 3.

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

See general directions for use of Meta SPC 3.

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

See general directions for use of Meta SPC 3.

4.2. Use description

Table 2

Use #3.2 – Hygienic Handrub, Professional – BP03

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	n/a
Target organism(s) (including development stage)	Common name: Bacteria Common name: Yeasts Common name: Enveloped viruses
Field(s) of use	Indoor use In hospitals and other areas, if a high level of hand hygiene is necessary, e.g.: — Domestic use (home care etc.); — Institutional use (research etc.); — Industrial applications, e.g. food, cosmetic, pharmaceutical industry etc.; — Restaurants and large-scale/canteen kitchens; — Recreational areas.
Application method(s)	Method: Handrub (hygienic), gel dispensing onto hands Detailed description: The product is ready to use (RTU).
Application rate(s) and frequency	Application Rate: Adult: 3 ml. The amount of gel shall resemble the size of a large-sized coin (The number of pumps with the dosing system equivalent to 3 ml of the product to be specified by the authorisation holder within the product information). RTU Number and timing of application: Frequency: Adult: Typically 25 applications per day.
Category(ies) of users	Professional
Pack sizes and packaging material	— 1 000 ml bottle – HDPE + PP screw cap (with and without LDPE nozzle) — 1 000 ml bottle – HDPE + PP/PE dosing cap — 500 ml bottle – HDPE + PP screw cap (with and without LDPE nozzle) — 150 ml bottle – HDPE + PP screw flip top cap — 100 ml bottle – HDPE + PP screw flip top

4.2.1. Use-specific instructions for use

The product shall be used on visibly clean hands. If hands are dirty, wash with soap and water, rinse and dry before applying the product.

The product is ready-to-use. The product shall be either applied directly or used in a dispenser or with a pump.

Step 1: Apply the following amount of disinfectant:

— Adult: 3 ml

Rub into palm of hand. Rub palm to palm to spread disinfectant over entire hands and fingers.

Step 2: Rub the back of your left hand with the palm of the right hand. Reverse and repeat action.

Step 3: Open fingers and rub the finger webs. Reverse and repeat action.

Step 4: Rub palm to palm with fingers interlocked (5 times).

Step 5: Rub thumb of each hand using a rotating movement.

Step 6: Rub the tips of the fingers against the opposite palm using circular movement. Rub wrist with both hands. Allow hands to dry completely.

Keep wet for 30 sec against bacteria, yeast and enveloped viruses.

Do not rinse.

Repeat if renewed hand disinfection is required.

Make sure that the applied product is completely dried before entering a room or area where people will stay for a longer period of time.

4.2.2. *Use-specific risk mitigation measures*

See general directions for use of Meta SPC 3.

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 general directions for use of Meta SPC 3.

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

See general directions for use of Meta SPC 3.

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

See general directions for use of Meta SPC 3.

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 3

5.1. **Instructions for use**

See use-specific instructions for each use.

Comply with the instructions for use.

5.2. **Risk mitigation measures**

All handling shall only take place in well-ventilated areas.

In case of skin dryness, use appropriate skin care lotion.

Avoid contact with eyes.

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

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

In case of fire: Use CO₂, dry chemical, or foam to extinguish.

Dispose of contents/container according to local / regional / national / international regulations.

First aid:

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

IF SWALLOWED: Rinse mouth. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

IF ON SKIN: If irritation occurs wash with water and seek medical advice. In cases of unintentional skin exposure: wash with water.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

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

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements

Waste disposal code: 070604

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

Keep out of reach of children and non-target animals/pets.

Store in the dark. Keep cool. Do not store at temperatures exceeding 35 °C.

Shelf life: 3 years

6. OTHER INFORMATION

Please be aware of the European reference value of 129,2 mg/m³ for the active substance propan-2-ol (CAS No: 67-63-0) which was used for the risk assessment of the biocidal product family.

Professionals (including industrial, professionals) mean trained professional if this is required by national legislation.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

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

Trade name(s)	Lotio Sept Gel	Market area: EU
	Alco Gel	Market area: EU
	Care Sept Gel	Market area: EU
	Lotio-Sept-Gel	Market area: EU
	Manorapid gel	Market area: EU
	Op Sept Gel	Market area: EU
	SeptoMed Gel	Market area: EU
	Sicu Gel	Market area: EU
	Sicu Sept Gel	Market area: EU
	Teva Lotio Sept Gel	Market area: EU

	Tork Alcohol Gel	Market area: EU			
	Alcohol Gel	Market area: EU			
	Alcoman-Gel	Market area: EU			
	Alkohol Gel	Market area: EU			
	antiseptic gel	Market area: EU			
	Deppe Gel	Market area: EU			
	Desinfektions-gel	Market area: EU			
	desinfizier-endes Handgel	Market area: EU			
	Händedesin-fektionsgel	Market area: EU			
	Handgel	Market area: EU			
	Hygienegel	Market area: EU			
	Hygienic Hand Gel	Market area: EU			
	Actoderm Gel	Market area: EU			
	Lotio Sept Gel perfume-free	Market area: EU			
	Lotio Sept Gel pur	Market area: EU			
	Lotio Sept Gel pure	Market area: EU			
	Manorapid gel pure	Market area: EU			
Authorisation number		EU-0033834-0005 1-3			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active substance	67-63-0	200-661-7	64 % (w/w)

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

Trade name(s)			Lotio Sept Gel Color	Market area: EU		
			Lotio Sept Gel blau	Market area: EU		
			Lotio Sept Gel blue	Market area: EU		
			OP Sept Gel Color	Market area: EU		
Authorisation number			EU-0033834-0006 1-3			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
Propan-2-ol		Active substance	67-63-0	200-661-7	64 % (w/w)	