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COMMISSION IMPLEMENTING REGULATION (EU) 2026/2411

of 30 October 2026

amending Implementing Regulation (EU) 2025/427 as regards administrative changes to the Union authorisation for the biocidal product family 'Orochemie hand disinfectants'

(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 50(2) thereof,

Whereas:

(1) On 4 March 2025, Commission Implementing Regulation (EU) 2025/427 ([2]) granted a Union authorisation, under number EU-0032838-0000, to Orochemie GmbH + Co. KG for the making available on the market and use of the biocidal product family 'Orochemie hand disinfectants'. The Annex to that Implementing Regulation provides the summary of product characteristics for that biocidal product family.

(2) Commission Implementing Regulation (EU) No 354/2013 ([3]) lays down the procedural rules for the different categories of changes referred to in Article 50(3) of Regulation (EU) No 528/2012.

(3) On 16 July 2025, Orochemie GmbH + Co. KG submitted to the European Chemicals Agency ('the Agency'), in accordance with Article 11(1) of Implementing Regulation (EU) 354/2013, a notification of administrative changes to the Union authorisation for the biocidal product family 'Orochemie hand disinfectants'. The notification was recorded in the Register for Biocidal Products ('Register') under case number BC-GS108932-24. The notified proposed changes to that authorisation concern the addition of a manufacturer (Shell Nederland Raffinaderij B.V.) and the removal of two manufacturers (AUG.Hedinger GmbH & co. KG and STOCKMEIER Holding GmbH), for the active substance propan-2-ol.

(4) On 12 August 2025, the Agency submitted to the Commission, in accordance with Article 11(3) of Implementing Regulation (EU) No 354/2013, an opinion ([4]) on the notified administrative changes to the Union authorisation for the biocidal product family 'Orochemie hand disinfectants'.

(5) In its opinion, the Agency concluded that the proposed changes are administrative changes as referred to in Article 3(1) point (aa), of Regulation (EU) No 528/2012 and as specified in Title 1, Section 1 and 2, of the Annex to Implementing Regulation (EU) No 354/2013, and that, after the implementation of the changes, the conditions of Article 19 of Regulation (EU) No 528/2012 will still be met.

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

([2]) Commission Implementing Regulation (EU) 2025/427 of 4 March 2025 granting a Union authorisation for the biocidal product family Orochemie hand disinfectants in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L, 2025/427, 6.3.2025, ELI: http://data.europa.eu/eli/reg_impl/2025/427/oj).

([3]) Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4, ELI: http://data.europa.eu/eli/reg_impl/2013/354/oj).

([4]) ECHA Opinion N° UAD-C-1848267-15-00/F of 12 August 2025 on administrative changes of the Union authorisation for the biocidal product family 'Orochemie hand disinfectants'. https://echa.europa.eu/fi/opinions-on-applications-for-union-authorisation.

(6) On 12 August 2025, the Agency transmitted to the Commission a revised summary of the product characteristics for the biocidal product family 'Orochemie hand disinfectants' in all official languages of the Union, covering the administrative changes applied for, in accordance with Article 11(6) of Implementing Regulation (EU) No 354/2013.

(7) It is therefore appropriate to amend the Union authorisation for the biocidal product family 'Orochemie hand disinfectants' to introduce the administrative changes requested by Orochemie GmbH + Co. KG.

(8) In order to enhance clarity and to ease the access of users and interested parties to the consolidated version of the summary of the product characteristics which is to be published by the Agency, the Annex to Implementing Regulation (EU) 2025/427 should be replaced in its entirety.

(9) Implementing Regulation (EU) 2025/427 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2025/427 is replaced by the text set out in the Annex to this Regulation.

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, 30 October 2026.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT FAMILY

orochemie hand disinfectants

Product type(s)

PT01: Human hygiene

Authorisation number

EU-0032838-0000

R4BP asset number

EU-0032838-0000

PART I

FIRST INFORMATION LEVEL

1 ADMINISTRATIVE INFORMATION

1.1 **Family name**

Name	orochemie hand disinfectants

1.2 **Product type(s)**

Product type(s)	PT01: Human hygiene

1.3 **Authorisation holder**

Name and address of the authorisation holder	Name	orochemie GmbH + Co. KG
	Address	Max-Planck-Str. 27 70806 Kornwestheim DE
Authorisation number	EU-0032838-0000	
R4BP asset number	EU-0032838-0000	
Date of the authorisation	26/03/2025	
Expiry date of the authorisation	28/02/2035	

1.4 **Manufacturer(s) of the product**

Name of manufacturer	orochemie GmbH & Co.KG
Address of manufacturer	Max-Planck-Str. 27 70806 Kornwestheim Germany
Location of manufacturing sites	orochemie GmbH & Co.KG site 1 Max-Planck-Str. 27 70806 Kornwestheim Germany

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

Active substance	Propan-1-ol
Name of manufacturer	BASF SE
Address of manufacturer	67056 Ludwigshafen Germany
Location of manufacturing sites	BASF SE site 1 Carl-Bosch-Strasse 38 67056 Ludwigshafen Germany

Active substance	Propan-1-ol
Name of manufacturer	Sasol Chemie GmbH & Co. KG
Address of manufacturer	Anckelmannsplatz 1 20537 Hamburg Germany
Location of manufacturing sites	Sasol Chemie GmbH & Co. KG site 1 PDP Kruger Street 2302 Secunda South Africa

Active substance	Propan-2-ol
Name of manufacturer	INEOS Solvents Germany GmbH
Address of manufacturer	Römerstraße 733 47443 Moers Germany
Location of manufacturing sites	INEOS Solvents Germany GmbH site 1 Römerstraße 733 47443 Moers Germany

Active substance	Propan-2-ol
Name of manufacturer	Shell Nederland Raffinaderij B.V.
Address of manufacturer	Vondelingenweg 601, Postbus 3000 3190 KK Rotterdam Netherlands (the)
Location of manufacturing sites	Shell Nederland Raffinaderij B.V. Vondelingenweg 601 3196 KK Vondelingenplaat Netherlands (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-1-ol		Active substance	71-23-8	200-746-9	26 - 26 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	47 - 47 % (w/w)

2.2 **Type(s) of formulation**

Formulation type(s)	AL Any other liquid

PART II.

SECOND INFORMATION LEVEL META SPC(S)

1 META SPC 1 ADMINISTRATIVE INFORMATION

1.1 **Meta SPC 1 identifier**

Identifier	meta SPC 1

1.2 **Suffix to the authorisation number**

Number	1-1

1.3 **Product type(s)**

Product type(s)	PT01: Human hygiene

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-1-ol		Active substance	71-23-8	200-746-9	26 - 26 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	47 - 47 % (w/w)

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

Formulation type(s)	AL Any other liquid

3 HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	H225: Highly flammable liquid and vapour. H319: Causes serious eye irritation. H336: May cause drowsiness or dizziness. EUH066: Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P103: Read carefully and follow all instructions. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233: Keep container tightly closed. P240: Ground and bond container and receiving equipment.

	P241: Use explosion-proof electrical equipment. P242: Use non-sparking tools. P243: Take actions to prevent static discharges. P261: Avoid breathing vapours. P271: Use only outdoors or in a well-ventilated area. P280: Wear eye protection. P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312: Call a POISON CENTER if you feel unwell. P337+P313: If eye irritation persists: Get medical advice. P370+P378: In case of fire: Use water spray jet to extinguish. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P403+P235: Store in a well-ventilated place. Keep cool. P405: Store locked up. P501: Dispose of contents hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. P501: Dispose of container hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

4 AUTHORISED USE(S) OF THE META SPC

4.1 **Use description**

hygienic hand rub - non-professional user

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: Yeast Common name: Bacteria Common name: Mycobacteria Common name: Viruses (limited spectrum virucidal activity) Common name: Enveloped viruses
Field(s) of use	indoor use Use in health care and health care facilities, domestic, institutional, veterinary, local authorities, nail and cosmetics studios, beauty and wellness salons, tattoo studios, hotels, funeral parlour.
Application method(s)	Method: Rubbing Detailed description:

Application rate(s) and frequency	Application Rate: Application amount of the formulated product according to product information: — per hygienic hand rub: 3 ml (the amount of liquid should resemble the size of a large-sized coin) equal to 2 pumps with the dosing system Contact time: — Bacteria and yeast: 30 s — Mycobactericidal/tuberculocidal activity: 30 s — Limited spectrum virucidal activity: 2 min (1,5 min on visibly clean hands) — Activity against enveloped viruses: 30 s Dry hands should be completely moistened with the undiluted product. ready-to-use product Number and timing of application: Non-professional use: Do not exceed 10 applications per day.
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	50 ml, oval, bottle white + white coloured lid (flip-top lid) 75 ml, oval, bottle white + white coloured lid (flip-top lid) 100 ml, oval, bottle white + white coloured lid (flip-top lid) 125 ml, oval, bottle white + white coloured lid (flip-top lid) 500 ml square bottle opaque + white coloured lid or pink coloured lid (flip-top lid) 500 ml square bottle white + white coloured lid or pink coloured lid (flip-top lid) Ophard 500 ml KX bottle, opaque + Ophard NUX S spray pump (shower head) Ophard 500 ml hygiene packaging, opaque + Ophard pump 500 ml round bottle opaque + white coloured lid (screw cap) 800 ml square bottle opaque + white coloured or pink coloured lid (flip-top lid) 1 litre square bottle opaque + white coloured lid or pink coloured lid (flip-top lid) 1 litre square bottle opaque + white coloured lid (screw cap) 1 litre square bottle white + white coloured lid or pink coloured lid (flip-top lid) 1 litre square bottle white + white coloured lid (screw cap) Ophard 1 litre KX bottle, opaque + Ophard NUX S spray pump (shower head) Ophard 1 litre hygiene packaging, opaque + Ophard pump All bottles: polyethylene (PE) Lids: PE or polypropylene (PP)

4.1.1 *Use-specific instructions for use*

Comply with the instructions for use.

The biocidal product is always applied undiluted. For hygienic hand rub, completely moisten dry hands with 3 ml and keep moist for 30 seconds to 2 minutes. When used in food preparation and handling (restaurants and large-scale/canteen kitchens, grocery shops, butcher, etc.) only use on visibly clean hands. For use in medical area against viruses, only use on visibly clean hands.

4.1.2 *Use-specific risk mitigation measures*

Use for children only under supervision of an adult. Apply the amount on your own hand first and rub the product on child's/toddler's hand. Make sure that the child/toddler does not touch eyes or mouth before the product has dried.

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.

Avoid unnecessary contact to skin.

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

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*

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

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

See general directions for use

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

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

4.2 **Use description**

hygienic and surgical hand rub - professional user

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	Hygienic hand disinfection by hand rubbing without rinsing. Surgical hand disinfection by hand rubbing without rinsing in health care (including ambulance) and veterinary health care.
Target organism(s) (including development stage)	Common name: Yeast Common name: Bacteria Common name: Mycobacteria Common name: Viruses (limited spectrum virucidal activity) Common name: Enveloped viruses
Field(s) of use	indoor use Use in health care and health care facilities (including ambulance), domestic, institutional, veterinary, industry, food preparation and handling (restaurants and large-scale/canteen kitchens, grocery shops, butcher, etc.), local authorities, building cleaning services, nail and cosmetics studios, beauty and wellness salons, tattoo studios, hotels, funeral parlour Surgical hand disinfection by hand rubbing without rinsing in health care (including ambulance) and veterinary health care.
Application method(s)	Method: Rubbing Detailed description:

Product type	PT01: Human hygiene
Application rate(s) and frequency	Application Rate: Application amount of the formulated product according to product information: — per hygienic hand rub: 3 ml — per surgical hand rub: 10 ml (100 %) Contact time: Hygienic hand rub: — Bacteria and yeasts: 30 s — Mycobactericidal/tuberculocidal activity: 30 s — Limited spectrum virucidal activity: 2 min (1,5 min on visibly clean hands) — Activity against enveloped viruses: 30 s. Surgical hand rub: 1,5 min Dry hands should be completely moistened with the undiluted product. ready-to-use product Number and timing of application: Professional use: Use up to 25 times per 8-hour shift
Category(ies) of users	professional
Pack sizes and packaging material	50 ml, oval, bottle white + white coloured lid (flip-top lid) 75 ml, oval, bottle white + white coloured lid (flip-top lid) 100 ml, oval, bottle white + white coloured lid (flip-top lid) 125 ml, oval, bottle white + white coloured lid (flip-top lid) 500 ml square bottle opaque + white coloured lid or pink coloured lid (flip-top lid) 500 ml square bottle white + white coloured lid or pink coloured lid (flip-top lid) Ophard 500 ml KX bottle, opaque + Ophard NUX S spray pump (shower head) Ophard 500 ml hygiene packaging, opaque + Ophard pump 500 ml round bottle opaque + white coloured lid (screw cap) 800 ml square bottle opaque + white coloured or pink coloured lid (flip-top lid) 1 litre square bottle opaque + white coloured lid or pink coloured lid (flip-top lid) 1 litre square bottle opaque + white coloured lid (screw cap) 1 litre square bottle white + white coloured lid or pink coloured lid (flip-top lid) 1 litre square bottle white + white coloured lid (screw cap) Ophard 1 litre KX bottle, opaque + Ophard NUX S spray pump (shower head) Ophard 1 litre hygiene packaging, opaque + Ophard pump only for hygienic hand rub: 2,5 litre bottle white + pink coloured lid (screw cap) 5 litre canister white + white coloured lid (screw cap) 10 litre canister white + white coloured lid (screw cap) 220 litre barrel 1000 litre IBC container All bottles: PE Lids: PE or PP

4.2.1 *Use-specific instructions for use*

The biocidal product is always applied undiluted. For surgical hand rub, completely moisten previously cleaned and dried hands and forearms with biocidal product and continue to apply it for 1,5 minutes to keep the skin moist (at least 10 ml total).

For hygienic hand rub completely moisten the hands with biocidal product and keep moist for 30 seconds to 2 minutes. When used for hygienic hand rub in food preparation and handling (restaurants and large-scale/canteen kitchens, grocery shops, butcher, etc.) only use on visibly clean hands. For use in medical area against viruses, only use on visibly clean hands.

Do not refill or decant products used as surgical hand rub.

For refilling, a funnel must be applied.

4.2.2 *Use-specific risk mitigation measures*

The use of eye protection during refilling of the application bottles is mandatory.

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

See general directions for use

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

See general directions for use

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

See general directions for use

5 GENERAL DIRECTIONS FOR USE OF THE META SPC 1

5.1 **Instructions for use**

-

5.2 **Risk mitigation measures**

Ensure adequate ventilation during the application.

Avoid contact with eyes.

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

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. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. If symptoms: Call 112 or an 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 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.

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

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

Do not allow to enter into surface water or drains. Do not allow to enter into soil or subsoil. To cleaning up: absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Collect in closed and suitable containers for disposal.

Dispose of contents/container to an approved waste disposal plant. Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

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

Shelf-life: 48 months

Protect from direct sunlight.

Keep container tightly closed.

Store in a well ventilated place. Keep cool.

6 OTHER INFORMATION

Please be aware of the European reference values of 129,28 mg/m³ for the active substance propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for the biocidal product family.

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)	C 14
	oro® med
	HD 410 plus
	HD 413 plus
	HD 400 plus
	HD 420 plus
Authorisation number	EU-0032838-0001 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active substance	71-23-8	200-746-9	26 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	47 % (w/w)

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

Trade name(s)	C 10
	HD 410
	HD 413
	Dürr System-Hygiene HD 410 hand disinfection
	HD 400
	HD 420
	C 10 hand disinfection
	HD 410 hand disinfection
Authorisation number	EU-0032838-0002 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active substance	71-23-8	200-746-9	26 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	47 % (w/w)

1 META SPC 2 ADMINISTRATIVE INFORMATION

1.1 **Meta SPC 2 identifier**

Identifier	meta SPC 2

1.2 **Suffix to the authorisation number**

Number	1-2

1.3 **Product type(s)**

Product type(s)	PT01: Human hygiene

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-1-ol		Active substance	71-23-8	200-746-9	26 - 26 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	47 - 47 % (w/w)

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

Formulation type(s)	AL Any other liquid

3 HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	H226: Flammable liquid and vapour. H319: Causes serious eye irritation. H336: May cause drowsiness or dizziness. EUH066: Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P103: Read carefully and follow all instructions. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233: Keep container tightly closed. P240: Ground and bond container and receiving equipment. P241: Use explosion-proof electrical equipment. P242: Use non-sparking tools. P243: Take actions to prevent static discharges. P261: Avoid breathing vapours. P271: Use only outdoors or in a well-ventilated area. P280: Wear eye protection. P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312: Call a POISON CENTER if you feel unwell. P337+P313: If eye irritation persists: Get medical advice. P370+P378: In case of fire: Use water spray jet to extinguish. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P403+P235: Store in a well-ventilated place. Keep cool. P405: Store locked up. P501: Dispose of contents hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. P501: Dispose of container hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

4 AUTHORISED USE(S) OF THE META SPC

4.1 **Use description**

hygienic hand rub - non-professional user

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	

Product type	PT01: Human hygiene
Target organism(s) (including development stage)	Common name: Yeast Common name: Bacteria Common name: Mycobacteria Common name: Viruses (limited spectrum virucidal activity) Common name: Enveloped viruses
Field(s) of use	indoor use Use in health care and health care facilities, domestic, institutional, veterinary, local authorities, nail and cosmetics studios, beauty and wellness salons, tattoo studios, hotels, funeral parlour.
Application method(s)	Method: Rubbing Detailed description:
Application rate(s) and frequency	Application Rate: Application amount of the formulated product according to product information: — per hygienic hand rub: 3 ml (the amount of liquid should resemble the size of a large-sized coin) equal to 2 pumps with the dosing system Contact time: — Bacteria and yeast: 30 s — Mycobactericidal/tuberculocidal activity: 30 s — Limited spectrum virucidal activity: 2 min (1,5 min on visibly clean hands) — Activity against enveloped viruses: 30 s. Dry hands should be completely moistened with the undiluted product. ready-to-use product Number and timing of application: Non-professional use: Do not exceed 10 applications per day.
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	50 ml, oval, bottle white + white coloured lid (flip-top lid) 75 ml, oval, bottle white + white coloured lid (flip-top lid) 100 ml, oval, bottle white + white coloured lid (flip-top lid) 125 ml, oval, bottle white + white coloured lid (flip-top lid) 500 ml square bottle opaque + white coloured lid or pink coloured lid (flip-top lid) 500 ml square bottle white + white coloured lid or pink coloured lid (flip-top lid) Ophard 500 ml KX bottle, opaque + Ophard NUX S spray pump (shower head) Ophard 500 ml hygiene packaging, opaque + Ophard pump 500 ml round bottle opaque + white coloured lid (screw cap) 800 ml square bottle opaque + white coloured or pink coloured lid (flip-top lid) 1 litre square bottle opaque + white coloured lid or pink coloured lid (flip-top lid) 1 litre square bottle opaque + white coloured lid (screw cap) 1 litre square bottle white + white coloured lid or pink coloured lid (flip-top lid) 1 litre square bottle white + white coloured lid (screw cap) Ophard 1 litre KX bottle, opaque + Ophard NUX S spray pump (shower head) Ophard 1 litre hygiene packaging, opaque + Ophard pump All bottles: PE Lids: PE or PP

4.1.1 *Use-specific instructions for use*

Comply with the instructions for use.

The biocidal product is always applied undiluted. For hygienic hand rub, completely moisten dry hands with 3 ml and keep moist for 30 seconds to 2 minutes. When used in food preparation and handling (restaurants and large-scale/canteen kitchens, grocery shops, butcher, etc.) only use on visibly clean hands. For use in medical area against viruses, only use on visibly clean hands.

4.1.2 *Use-specific risk mitigation measures*

Use for children only under supervision of an adult. Apply the amount on your own hand first and rub the product on child's/toddler's hand. Make sure that the child/toddler does not touch eyes or mouth before the product has dried.

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.

Avoid unnecessary contact to skin.

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

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*

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

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

See general directions for use

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

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

4.2 **Use description**

hygienic and surgical hand rub - professional user

Product type	PT01: Human hygiene
Where relevant, an exact description of the authorised use	Hygienic hand disinfection by hand rubbing without rinsing. Surgical hand disinfection by hand rubbing without rinsing in health care (including ambulance) and veterinary health care.
Target organism(s) (including development stage)	Common name: Yeast Common name: Bacteria Common name: Mycobacteria Common name: Viruses (limited spectrum virucidal activity) Common name: Enveloped viruses
Field(s) of use	indoor use Use in health care and health care facilities (including ambulance), domestic, institutional, veterinary, industry, food preparation and handling (restaurants and large-scale/canteen kitchens, grocery shops, butcher, etc.), local authorities, building cleaning services, nail and cosmetics studios, beauty and wellness salons, tattoo studios, hotels, funeral parlour Surgical hand disinfection by hand rubbing without rinsing in health care (including ambulance) and veterinary health care.

Product type	PT01: Human hygiene
Application method(s)	Method: Rubbing Detailed description:
Application rate(s) and frequency	Application Rate: Application amount of the formulated product according to product information: — per hygienic hand rub: 3 ml — per surgical hand rub: 10 ml (100 %) Contact time: Hygienic hand rub: — Bacteria and yeasts: 30 s — Mycobactericidal/tuberculocidal activity: 30 s — Limited spectrum virucidal activity: 2 min (1,5 min on visibly clean hands) — Activity against enveloped viruses: 30 s Surgical hand rub: 1,5 min Dry hands should be completely moistened with the undiluted product. ready-to-use product Number and timing of application: Professional use: Use up to 25 times per 8-hour shift
Category(ies) of users	professional
Pack sizes and packaging material	50 ml, oval, bottle white + white coloured lid (flip-top lid) 75 ml, oval, bottle white + white coloured lid (flip-top lid) 100 ml, oval, bottle white + white coloured lid (flip-top lid) 125 ml, oval, bottle white + white coloured lid (flip-top lid) 500 ml square bottle opaque + white coloured lid or pink coloured lid (flip-top lid) 500 ml square bottle white + white coloured lid or pink coloured lid (flip-top lid) Ophard 500 ml KX bottle, opaque + Ophard NUX S spray pump (shower head) Ophard 500 ml hygiene packaging, opaque + Ophard pump 500 ml round bottle opaque + white coloured lid (screw cap) 800 ml square bottle opaque + white coloured or pink coloured lid (flip-top lid) 1 litre square bottle opaque + white coloured lid or pink coloured lid (flip-top lid) 1 litre square bottle opaque + white coloured lid (screw cap) 1 litre square bottle white + white coloured lid or pink coloured lid (flip-top lid) 1 litre square bottle white + white coloured lid (screw cap) Ophard 1 litre KX bottle, opaque + Ophard NUX S spray pump (shower head) Ophard 1 litre hygiene packaging, opaque + Ophard pump only for hygienic hand rub: 2,5 litre bottle white + pink coloured lid (screw cap) 5 litre canister white + white coloured lid (screw cap) 10 litre canister white + white coloured lid (screw cap) 220 litre barrel 1000 litre IBC container All bottles: PE Lids: PE or PP

4.2.1 *Use-specific instructions for use*

The biocidal product is always applied undiluted. For surgical hand rub, completely moisten previously cleaned and dried hands and forearms with biocidal product and continue to apply it for 1,5 minutes to keep the skin moist (at least 10 ml total).

For hygienic hand rub completely moisten the hands with biocidal product and keep moist for 30 seconds to 2 minutes. When used for hygienic hand rub in food preparation and handling (restaurants and large-scale/canteen kitchens, grocery shops, butcher, etc.) only use on visibly clean hands. For use in medical area against viruses, only use on visibly clean hands.

Do not refill or decant products used as surgical hand rub.

For refilling, a funnel must be applied.

4.2.2 *Use-specific risk mitigation measures*

The use of eye protection during refilling of the application bottles is mandatory.

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

See general directions for use

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

See general directions for use

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

See general directions for use

5 GENERAL DIRECTIONS FOR USE OF THE META SPC 2

5.1 **Instructions for use**

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5.2 **Risk mitigation measures**

Ensure adequate ventilation during the application.

Avoid contact with eyes.

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

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. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. If symptoms: Call 112 or an 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 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.

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

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

Do not allow to enter into surface water or drains. Do not allow to enter into soil or subsoil. To cleaning up: absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Collect in closed and suitable containers for disposal.

Dispose of contents/container to an approved waste disposal plant. Dispose of contents to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Dispose of container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

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

Shelf-life: 48 months

Protect from direct sunlight.

Keep container tightly closed.

Store in a well ventilated place. Keep cool.

6 OTHER INFORMATION

Please be aware of the European reference values of 129,28 mg/m³ for the active substance propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for the biocidal product family.

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)	C 12
	oro® pure
	oro® care
	oro® Händedesinfektion
	HD 410 essential
	HD 413 essential
	HD 400 essential
	HD 420 essential
Authorisation number	EU-0032838-0003 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active substance	71-23-8	200-746-9	26 % (w/w)
Propan-2-ol		Active substance	67-63-0	200-661-7	47 % (w/w)