

Nr. 154/11 din 11.11.2024

Către: Centrul pentru Achizitii Publice Centralizate în Sănătate,

Numărul unic de identificare al procedurii de achiziție:

ocds-b3wdp1-MD-1722922885780/21266225,

*”Achiziționarea centralizată a Dezinfectanților conform necesităților IMSP -
beneficiari pentru anul 2025”.*

DEMERS

Ca răspuns la solicitarea Dumneavoastră, cu privire la prezentarea clarificărilor nr. Rg02 - 3988 din data de 06.11.2024, în cadrul procedurii de achiziție nr. **ocds-b3wdp1-MD-1722922885780/21266225,** privind *”Achiziționarea centralizată a Dezinfectanților conform necesităților IMSP - beneficiari pentru anul 2025”*, SRL “Endo-Chirurgie”, Vă comunică următoarele:

- Ca urmare a solicitării prezentării suplimentare a actelor pentru lotul nr. 22 - Soluție de training sau testare a dezinfecției mâinilor, producătorul Sculke&Mayr GMBH, ne-a comunicat faptul că, Soluția de training sau testare a dezinfecției mâinilor Schulke optics, cod produs 172001, a fost scos din producție, însă a fost înlocuit cu Schülke optics concentrate 10 ml, cod produs 70003662, pentru care Vă prezentăm actele solicitate suplimentar.

Anexe: 14 (paizprezece) file.

Cu respect,
Administrator

Victor GHEREG

Safety data sheet

according to 1907/2006/EC, Article 31

Revision: 26.04.2023

1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** *Schülke Optics Concentrate*

- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** *Stamp pad ink (hand)*
- **Details of the supplier of the safety data sheet**
- **Supplier product:**
*Allergen Consultancy BV, Oosteinde 85d, 3925 LB Scherpenzeel
The Netherlands
Tel +31 332770571
info@allergenconsultancy.nl*
- **Manufacturer ink (110 UV invisible):**
*Noris-Color GmbH, Ziegelhüttener Str. 1, D-95326 KULMBACH
Germany*

Distributed by Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt (Deutschland) Tel.: +49 (0)40/ 52100-0 e-mail: ChemicalCompliance@schuelke.com

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified, according to the CLP regulation.

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** *Void*
- **Hazard pictograms** *Void*
- **Signal word** *Void*
- **Hazard statements** *Void*
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

3 Composition/information on ingredients

- **Chemical characterisation:** *Mixtures*
- **Description:** *Mixture of substances listed below with nonhazardous additions.*

· **Dangerous components:**

CAS: 56-81-5	glycerol	50-100%
EINECS: 200-289-5	substance with a Community workplace exposure limit	
CAS: 112-34-5	2-(2-butoxyethoxy)ethanol	2.5-10%
EINECS: 203-961-6	◊ Eye Irrit. 2, H319	

- **Additional information:** *For the wording of the listed hazard phrases refer to section 16.*

4 First aid measures

- **Description of first aid measures**
- **General information:** *No special measures required.*
- **After inhalation:** *Supply fresh air; consult doctor in case of complaints.*
- **After skin contact:** *Generally the product does not irritate the skin.*
- **After eye contact:** *Rinse opened eye for several minutes under running water.*
- **After swallowing:**
*Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.*

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- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

56-81-5 glycerol

WEL Long-term value: 10 mg/m³

112-34-5 2-(2-butoxyethoxy)ethanol

WEL Short-term value: 101.2 mg/m³, 15 ppm
Long-term value: 67.5 mg/m³, 10 ppm

- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.

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· **Protection of hands:**

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:** Goggles recommended during refilling

9 Physical and chemical properties

· **Information on basic physical and chemical properties**· **General Information**· **Appearance:**

· Form:	Fluid
· Colour:	According to product specification
· Odour:	Characteristic
· Odour threshold:	Not determined.

· **pH-value:** Not determined.· **Change in condition**

· Melting point/freezing point:	Undetermined.
· Initial boiling point and boiling range:	99 °C

· **Flash point:** 101 °C· **Flammability (solid, gas):** Not applicable.· **Ignition temperature:** 400 °C· **Decomposition temperature:** Not determined.· **Auto-ignition temperature:** Product is not selfigniting.· **Explosive properties:** Product does not present an explosion hazard.· **Explosion limits:**

· Lower:	0.9 Vol %
· Upper:	Not determined.

· **Vapour pressure at 20 °C:** 23 hPa· **Density:** Not determined.· **Relative density** Not determined.· **Vapour density** Not determined.· **Evaporation rate** Not determined.· **Solubility in / Miscibility with water:**

Not miscible or difficult to mix.

· **Partition coefficient: n-octanol/water:** Not determined.· **Viscosity:**

· Dynamic:	Not determined.
· Kinematic:	Not determined.

· **Solvent content:**· **Organic solvents:** 62.2 %

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Water:	30.2 %
VOC (EC)	4.70 %
Solids content:	7.6 % (up to)
Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

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13 Disposal considerations

- **Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.
- **Waste disposal key:** Recommendation: 080111 (waste containing organic solvents)
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number
· ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name
· ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es)
· ADR, ADN, IMDG, IATA
· Class | Void |
| · Packing group
· ADR, IMDG, IATA | Void |
| · Environmental hazards:
· Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Void |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
- **Directive 2012/18/EU**
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 55
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**
H319 Causes serious eye irritation.
- **Department issuing SDS:** Product safety
- **Contact:** Hr. Wendland
- **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)

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VOC: Volatile Organic Compounds (USA, EU)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

GB

schülke optics concentrate

Fluorescent test concentrate for checking
wetting gaps during hand disinfection

we protect lives
worldwide

More safety in hand disinfection

Hand disinfection is a challenge especially for those responsible for hygiene in the health sector, where the average compliance rate is 50 percent. Effective hand disinfection is one of the most important factors in protecting patients optimally against healthcare-associated infections. However, disinfection must be carried out properly as required by the situation, without wetting gaps. Frequent sources of error are failure to use hand disinfectant in situations where it would be indicated, or an insufficient method of rubbing the hands.

With proper training, these sources of error can be identified!



The fluorescent method makes wetting gaps visible

Regular training with the fluorescent method has proven to be effective in raising hygiene awareness among employees and in increasing compliance with regulations, recommendations and codes of conduct.



The surface is consistently light – correct method!

No detection of wetting gaps as proof of hand disinfection carried out correctly.



Dark areas – wetting gaps are visible here

It is clearly visible that the areas, e.g. on the thumb and fingertips, are darkened. Showing that the wetting of the hands during disinfection was carried out insufficiently.



Using a combination of the fluorescent schülke optics concentrate and an alcohol-based hand disinfectant (e.g. desmanol® pure), hands are carefully rubbed in based on hand disinfection steps.

Afterwards, a special UV lamp (366 nm) reveals bright, luminous areas as well as dark areas on the skin. Lighter areas indicate better wetting and therefore more effective disinfection. The dark areas show the areas of the skin that received insufficient or no disinfectant.

An illustrative method with great learning success.

Detect
hygiene gaps
with
schülke.

How to start the training

Before starting the training, mix the schülke optics concentrate with an alcohol-based hand disinfectant (e.g. desmanol® pure). This will produce a ready-to-use training solution.

- 1 Pour the contents of the schülke optics 10 ml concentrate bottle into a full 500 ml bottle of schülke hand disinfectant.
- 2 Shake the content briefly.
- 3 Place the schülke optics training sticker on the 500 ml bottle in order to avoid confusion with regular hand disinfection content.



Now start the training with the prepared solution.

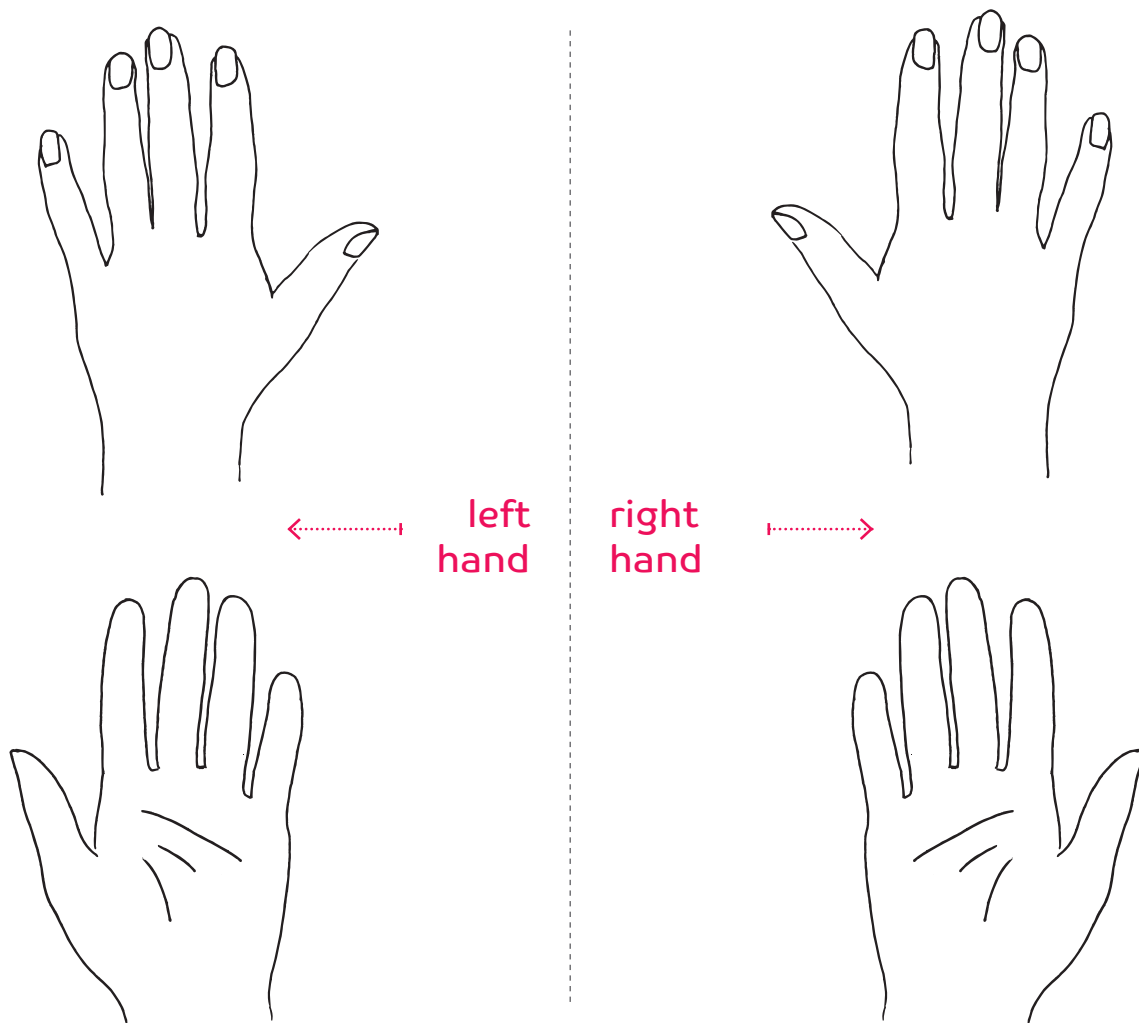
- 1 Remove 3 ml of the solution and rub it into your hands for 30 seconds. Follow the steps for hand disinfection (on page 6).*
- 2 Then hold your hands under the UV lamp. Areas with correct wetting appear glowing white. Areas with insufficient wetting are dark.
- 3 For documentation of the results, mark these areas on the sheet on the next page.
- 4 After the training, wash hands thoroughly.



* Do not use the training solution for hand disinfection.

The result in a matter of seconds

Here you can mark the areas with insufficient wetting during the schülke optics application. You will recognize them by the fact that they appear dark under the UV light.



The surface is consistently light = correct method!

Excellent! Both you and your patients are protected.



Few or numerous dark areas = visible wetting gaps.

Try again, paying special attention to the neglected areas.

For your safety and that of your patients.

The 6 steps of hygienic hand disinfection*

The hand disinfection steps are an effective way to achieve the most complete wetting of all parts of your hand surfaces within 30 seconds.

Palm on palm,
in addition to
the wrists.



Right palm on back
of the left hand –
and vice versa.



Outside of
the interlocked
fingers on
the opposite
palms.



Palm on palm
with interlocked,
spread fingers.



Rub the right thumb
in a circle in the
closed left palm –
and vice versa.



Rub closed fingertips
of the right hand
in the left palm –
and vice versa.



Dispense **3 ml** (= one handful) of hand disinfectant into the cupped, dry hand and rub it in for at least **30 seconds**. Pay special attention to **fingertips and thumbs**. The hands must remain moist during the entire application time; if necessary, dispense additional hand disinfectant.

* Exemplary presentation according to EN 1500. Hand disinfection can also be done independently.

Products to combine



schülke optics concentrate

Concentrate for combination with an alcohol-based hand disinfectant for training hand disinfection techniques.

- Fluorescent concentrate for checking hand disinfection and the results of the rub-in techniques
- Visualize wetting-gaps under UV lights
- Individual and group training, teaching sessions in training centers, in clinics and practices, and in testing, sampling, studies, and serial examinations
- Dermatologically tested
- Incl. training labels for the combination products



10 ml-bottle | Item no. 70003662

If spilled, there may be residues of fluorescent and alcohol. Do not allow to dry but clean up immediately. To ensure that the combination preparation is not used for hand disinfection, proper disposal must be ensured by the trainer.



desmanol® pure

Alcohol-based hand rub for hygienic and surgical hand disinfection with panthenol, without colour and perfume.

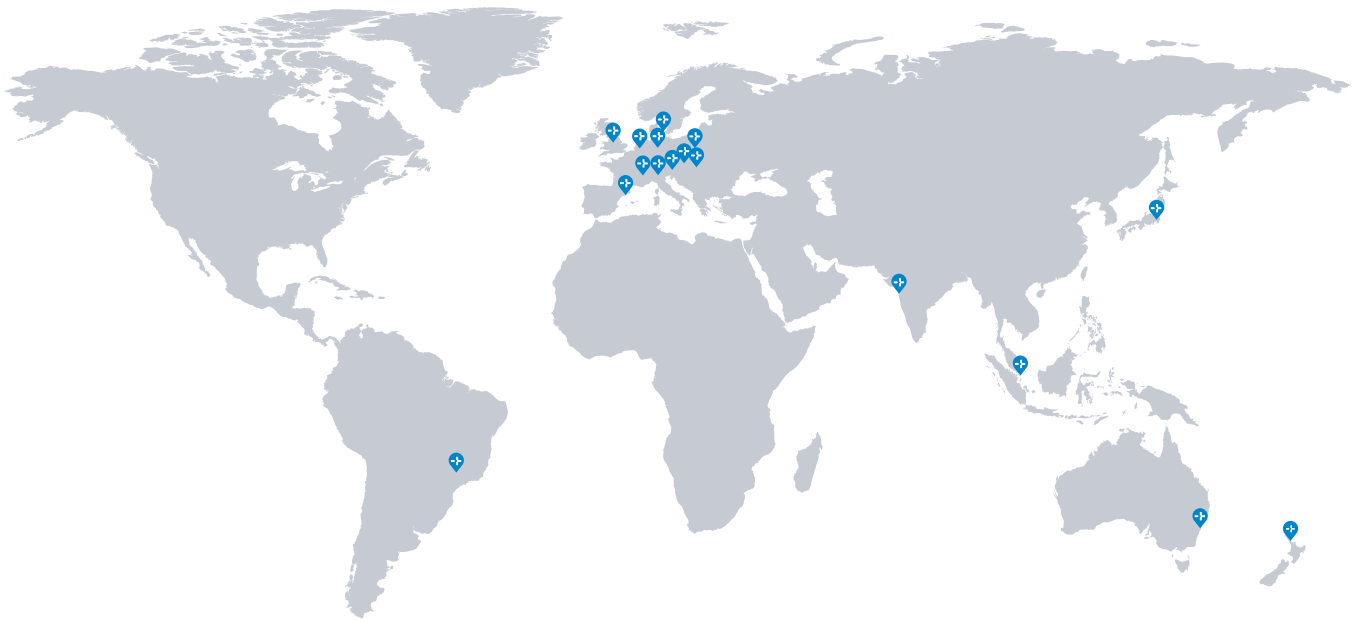
- All-season product: protects safely against infections all year round!
- Limited spectrum virucidal activity (in accordance with EN 14476)
- Outstanding skin feeling through an innovative skin care formula (ProPanthenol-complex)
- Care effect of the skin care formula clinically confirmed

500 ml-bottle | Item no. 125211 | PZN 13354024

Use disinfectants safely.
Always read the label and product information before use.

schülke group

we protect lives worldwide



schülke is present with over 20 subsidiaries and production sites in Germany (schülke), France (Bioxal) and Brazil (Vic Pharma). Companies with specific fields of application and markets such as Prosenio GmbH, Vesismin Health, and Wet Wipe A/S are also part of the schülke group.*

* This information is as of September 2023.

More information at www.schuelke.com

schülke →

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This product information is not
automatically updated.