**Et bilde som inneholder skjermbilde, sort

Automatisk generert beskrivelseApplication for approval of chemical disinfectant   
for technical use in health care and nursing**

Send the application to the Norwegian Medical Products Agency (NOMA), [desinfeksjonsmidler@noma.no](mailto:desinfeksjonsmidler@noma.no).

Fees will be billed by NOMA.

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| **Information about the applicant** |
| Applicant's name and postal address: |
| Manufacturer: |
| Contact person for the applicant: |
| Date: |
| Applicant's signature: |

If the product is supplied in more than one strength or formulation, an application for each strength or form must be submitted.

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| **Product information** |
| Name: |
| Dosage form: |
| Strength: |
| Reg. No: |
| Disinfective substances: |
| Concentration indicated by weight/volume: |
| Packages: |

Attachments that must be attached to the application:

1. Description of the product on form from NOMA (on the next page)
2. Labelling
3. Documentation
4. Summary of documentation

**DESCRIPTION OF THE PRODUCT – Appendix to application for approval of disinfectant for technical use in health care and nursing**

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| **Chemical information - composition of the product** | |
| Disinfective substance(s) | Concentration (preferably weight/vole) |
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| Excipients: | |
| Other comments: | |

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| **Chemical information - additional information about the product** |
| The preparation is ready to use  Yes  No |
| Must be diluted  Yes  No |
| Dilutant: |
| Dilutant ratio: |
| Shelf life of concentrate at room temperature: |
| Shelf life of use dilution: |
| Packaging (material): |
| Recommended tub for dilution: |

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| **Area of use** *(Disinfecting effect and material impact of the product considered as a whole)* |
| Metal and glass instruments  Suitable  Not suitable |
| Rubber and plastic remains  Suitable  Not suitable |
| Endoscopes, optical instruments  Suitable  Not suitable |
| Floor, walls, furniture, surface disinfection  Suitable  Not suitable |
| Specially suited for: |
| Has been in common use in health care in Norway?  Yes  No  If so, since year: |
| Has been in common use in other countries?  Yes  No  If so, which ones: |
| Used in the food industry?  Yes  No |

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| **Disinfectant effect - satisfactory effect** *(effect on microorganisms of ready-to-use solution, used according to instructions for use)* | | | |
| Gram-positive bacterias  Yes  No  Not documented | Gram-negative bacterias  Yes  No  Not documented | | Myco bacterias  Yes  No  Not documented |
| Bacterial spores  Yes  No  Not documented | Virus  Yes  No  Not documented | | Fungus  Yes  No  Not documented |
| Algae  Yes  No  Not documented | | Other: | |

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| **Disinfecting effect – effect** *(Effect on microorganisms of ready-to-use solution, used according to instructions for use)* | |
| Growth innhibitorry  Yes  No | Microbiocidal  Yes  No |
| Mechanism of effect: | Optimal pH |
| Contact time,  minimum      °C at room temperature      °C  minimum      °C at different temperature      °C | |
| Effect reduced by:  Organic matter  Yes  No  Inorganic salts, hard water  Yes  No  Detergents, phosphate/fatty acids  Yes  No  Other: | |

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| **Toxicological information - concentrated product** | | | |
| Low toxic  Highly toxic | | Any information on minimum toxic dose or maximum nontoxic dose to humans: | |
| Important symptoms of toxicity: | First aid: | | Antidote: |

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| **Toxicological information - ready-to-use solution** |
| Low toxic  Highly toxic |
| Long-term exposure toxic effects: |
| Irritating/corrosive on skin  Yes  No |
| Irritant on mucosa  Yes  No |
| Vapor from preparation irritating to eye/respiratory tract  Yes  No |
| May cause sensitization  Yes  No |
| Is a similar product registered as a medicinal product?  Yes  No |
| Annoying smell of ready-to-use preparation?  Essential  Weak  Nobody |
| Other information: |

| **Special tests for substances in the preparation** | | | |
| --- | --- | --- | --- |
| Substances | Mutagenic test | | Method |
|  | Yes | No |  |
|  | Yes | No |  |
|  | Yes | No |  |
| Substances | Carcinogenic test | | Species |
|  | Yes | No |  |
|  | Yes | No |  |
|  | Yes | No |  |
| Substances | Chronic toxicology | | Species |
|  | Yes | No |  |
|  | Yes | No |  |
|  | Yes | No |  |
| Substances | LD50 (mg/kg) | | Species |
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| **Environmental toxicology information** | | | |
| Biodegradability of the substances | | | |
| Substances | Rappid (days) | Slow (months) | Stable |
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| Other environmental toxicological information: | | | |

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| **Material impact, surface effect** |
| Material impact of ready-to-use solution with regular use according to the instructions for use:  Metal  Affected  Not affected  Plastic  Affect  Not affected  Rubber  Affected  Not affected  Lenses  Affected  Not affected  Fiber optic instruments  Affected  Not affected  Textiles  Affected  Not affected  Paint  Affected  Not affected  Discoloration (bleaching)  Affected  Not affected  Discoloration  Affected  Not affected |
| Other: |
| Deposition (for example, precipitation of polymeric compounds) on disinfected objects: |