**Application 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.

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[ ]  NoIf so, since year:       |
| Has been in common use in other countries?[ ]  Yes[ ]  NoIf 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      °Cminimum      °C at different temperature      °C |
| Effect reduced by:Organic matter[ ]  Yes[ ]  NoInorganic salts, hard water[ ]  Yes[ ]  NoDetergents, phosphate/fatty acids[ ]  Yes[ ]  NoOther:      |

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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** |
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| 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 affectedPlastic[ ]  Affect[ ]  Not affectedRubber[ ]  Affected[ ]  Not affectedLenses[ ]  Affected[ ]  Not affectedFiber optic instruments[ ]  Affected[ ]  Not affectedTextiles[ ]  Affected[ ]  Not affectedPaint[ ]  Affected[ ]  Not affectedDiscoloration (bleaching)[ ]  Affected[ ]  Not affectedDiscoloration[ ]  Affected[ ]  Not affected |
| Other:      |
| Deposition (for example, precipitation of polymeric compounds) on disinfected objects:      |