Practical Guide on Fast-Tracking the Supply of Disinfectants

during the COVID-19 Pandemic under the EU Biocides Rules

**Appendix 1**

**Overview of national measures to make disinfectants available on the EU market**

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**Version 1.1. -15 April 2020**

| **Country** | **Procedure** | **Active Substance** | **Product** | **PTs** | **Use controlled and limited to** | **Start date** | **Expiry date** | **Fees** | **Approach to Article 95** | **Approach to exports/**  **imports** | **Contact Details** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Austria** | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): Requires application. [Example of application](https://www.wko.at/service/umwelt-energie/bescheid-notfallzulassung-desinfektionsmittel.pdf) (in *German*) granted to Federal Economic Chamber (WKO) and its Members   No | |  | | --- | | Ethanol,  Propan-1-ol,  Propan-2-ol | | Products containing ethanol, Propan-1-ol and Propan-2-ol | PT 1  PT 2  PT 4 | Licensed producers of disinfectants and producers of ethanol.  In the example application companies need to be established in Austria | 19/03/2020 | 31/08/2020 | 12.000 €. | Substance may be purchased from entities not listed on Article 95 List, provided they comply with the quality criteria set out in the exemption. |  | Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology  [biozide@bmk.gv.at](mailto:biozide@bmk.gv.at) |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): *See above.*   No | Propan-2-ol | WHO II Formulation | PT 1  PT 2 | For pharmacies only | 12/03/2020 | 31/08/2020 |  |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): *See above.*   No | Propan-2-ol | WHO II Formulation | PT 1  PT 2 | For military pharmacies only | 23/03/2020 | 31/08/2020 |  |  |  |  |
| **Belgium** | **Article 55(1)?**  Yes   1. Notification: Notification 2020/140/B to Commission dated 19 March 2020 2. National law(s): [Arrêté royal 18 March 2020](http://www.ejustice.just.fgov.be/cgi/article_body.pl?language=fr&pub_date=2020-03-20&caller=summary&numac=2020040747#end) (in *French* and *Dutch*)   No | 70% alcohol | Following WHO formulations | PT 1 | Pharmacists and pharmacists in hospitals | 20/03/2020 |  | Free |  |  | Federal Public Service Health, Food Chain Safety and Environment - Directorate-General 5: Environment  [covid19.gestautor@health.fgov.be](mailto:covid19.gestautor@health.fgov.be)  Head of unit of the biocide unit of the Federal Public Service Environment:  [covid19.gestautor@health.fgov.be](mailto:covid19.gestautor@health.fgov.be) |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): Art. 21 of [Arrêté royal 4 April 2019](http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&table_name=loi&cn=2019040431) (in *French* and *Dutch*)   No | Peracetic acid (CAS-nr. 79-21-0) | ACIDOFOAM CF  Sopuroxid 3.2  [Full list of temporary authorisations](http://docs.health.belgium.be/COVID19/) delivered in the context of the fight against Covid-19 | PT 2 | Derogations granted to applicants  [Full list of authorisation holders for PT 2](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/07042020_liste_pt2_lutte_covid19.xlsx)  See [here](https://www.health.belgium.be/en/covid-19-temporary-authorisations#2) for details on obtaining derogations | 22/03/2020 | 18/09/2020 | Free |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): *See above.*   No | Propan-2-ol (CAS-nr 67-63-0) | Aero-Sense Alcohol Hand Gel 70%  [Full list of temporary authorisations](http://docs.health.belgium.be/COVID19/) delivered in the context of the fight against Covid-19 | PT 1 | Derogations granted to applicants  [Full list of authorisation holders for PT 1](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/07042020_liste_pt1_lutte_covid19.xlsx)  See [here](https://www.health.belgium.be/en/covid-19-temporary-authorisations#2) for details on obtaining derogations | 25/03/2020 | 21/09/2020 | Free |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): *See above.*   No | Propan-2-ol (CAS-nr 67-63-0) | ALCANAF  [Full list of temporary authorisations](http://docs.health.belgium.be/COVID19/) delivered in the context of the fight against Covid-19 | PT 1 | Derogations granted to applicants  [Full list of authorisation holders for PT 1](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/07042020_liste_pt1_lutte_covid19.xlsx)  See [here](https://www.health.belgium.be/en/covid-19-temporary-authorisations#2) for details on obtaining derogations | 26/03/2020 | 22/09/2020 | Free |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): *See above.*   No | Propan-2-ol (CAS-nr 67-63-0) | ALCOGEL  [Full list of temporary authorisations](http://docs.health.belgium.be/COVID19/) delivered in the context of the fight against Covid-19 | PT 1 | Derogations granted to applicants  [Full list of authorisation holders for PT 1](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/07042020_liste_pt1_lutte_covid19.xlsx)  See [here](https://www.health.belgium.be/en/covid-19-temporary-authorisations#2) for details on obtaining derogations | 01/04/2020 | 28/09/2020 | Free |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): *See above.*   No | Propan-2-ol (CAS-nr 67-63-0) | ALCO-JETH 75 Gel  [Full list of temporary authorisations](http://docs.health.belgium.be/COVID19/) delivered in the context of the fight against Covid-19 | PT 1 | Derogations granted to applicants  [Full list of authorisation holders for PT 1](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/07042020_liste_pt1_lutte_covid19.xlsx)  See [here](https://www.health.belgium.be/en/covid-19-temporary-authorisations#2) for details on obtaining derogations | 01/04/2020 | 28/09/2020 | Free |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): *See above.*   No | Propan-2-ol (CAS-nr 67-63-0) | ALCO-JETH 75 Liquid  [Full list of temporary authorisations](http://docs.health.belgium.be/COVID19/) delivered in the context of the fight against Covid-19 | PT 1 | Derogations granted to applicants  [Full list of authorisation holders for PT 1](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/07042020_liste_pt1_lutte_covid19.xlsx)  See [here](https://www.health.belgium.be/en/covid-19-temporary-authorisations#2) for details on obtaining derogations | 01/04/2020 | 28/09/2020 | Free |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): *See above.*   No | Hydrogen peroxide (CAS-nr. 7722-84-1)  Lactic acid (CAS-nr.79-33-4) | Alphades  [Full list of temporary authorisations](http://docs.health.belgium.be/COVID19/) delivered in the context of the fight against Covid-19 | PT 2 | Derogations granted to applicants  [Full list of authorisation holders for PT 2](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/07042020_liste_pt2_lutte_covid19.xlsx)  See [here](https://www.health.belgium.be/en/covid-19-temporary-authorisations#2) for details on obtaining derogations | 23/03/2020 | 19/09/2020 | Free |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): *See above.*   No | Propan-2-ol (CAS-nr. 67-63-0) | Autoactin  [Full list of temporary authorisations](http://docs.health.belgium.be/COVID19/) delivered in the context of the fight against Covid-19 | PT 1 | Derogations granted to applicants  [Full list of authorisation holders for PT 1](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/07042020_liste_pt1_lutte_covid19.xlsx)  See [here](https://www.health.belgium.be/en/covid-19-temporary-authorisations#2) for details on obtaining derogations | 22/03/2020 | 18/09/2020 | Free |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): *See above.*   No | Propan-2-ol (CAS-nr 67-63-0) | Gel hydroalcoolique mains 75%  [Full list of temporary authorisations](http://docs.health.belgium.be/COVID19/) delivered in the context of the fight against Covid-19 | PT 1 | Derogations granted to applicants  [Full list of authorisation holders for PT 1](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/07042020_liste_pt1_lutte_covid19.xlsx)  See [here](https://www.health.belgium.be/en/covid-19-temporary-authorisations#2) for details on obtaining derogations | 30/03/2020 | 26/09/2020 | Free |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): *See above.*   No | Propan-2-ol (CAS-nr 67-63-0) | HOLIS - spray hydro-alcoolique  [Full list of temporary authorisations](http://docs.health.belgium.be/COVID19/) delivered in the context of the fight against Covid-19 | PT 1 | Derogations granted to applicants  [Full list of authorisation holders for PT 1](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/07042020_liste_pt1_lutte_covid19.xlsx)  See [here](https://www.health.belgium.be/en/covid-19-temporary-authorisations#2) for details on obtaining derogations | 16/03/2020 | 12/09/2020 | Free |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): *See above.*   No | Hydrogen peroxide (CAS-nr. 7722-84-1)  Lactic acid (CAS-nr.79-33-4) | Laquick Pro  Desinfectz Pro  [Full list of temporary authorisations](http://docs.health.belgium.be/COVID19/) delivered in the context of the fight against Covid-19 | PT 2 | Derogations granted to applicants  [Full list of authorisation holders for PT 2](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/07042020_liste_pt2_lutte_covid19.xlsx)  See [here](https://www.health.belgium.be/en/covid-19-temporary-authorisations#2) for details on obtaining derogations | 23/03/2020 | 19/09/2020 | Free |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s):   *See above.*  No | Propan-2-ol (CAS-nr 67-63-0) | Nerta Manobac 100  [Full list of temporary authorisations](http://docs.health.belgium.be/COVID19/) delivered in the context of the fight against Covid-19 | PT 1 | Derogations granted to applicants  [Full list of authorisation holders for PT 1](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/07042020_liste_pt1_lutte_covid19.xlsx)  See [here](https://www.health.belgium.be/en/covid-19-temporary-authorisations#2) for details on obtaining derogations | 27/03/2020 | 23/09/2020 | Free |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): *See above.*   No | Propan-2-ol (CAS-nr. 67-63-0) | Ontsmettingsmiddel oppervlakken – Vloeistof  [Full list of temporary authorisations](http://docs.health.belgium.be/COVID19/) delivered in the context of the fight against Covid-19 | PT 2 | Derogations granted to applicants  [Full list of authorisation holders for PT 2](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/07042020_liste_pt2_lutte_covid19.xlsx)  See [here](https://www.health.belgium.be/en/covid-19-temporary-authorisations#2) for details on obtaining derogations | 26/03/2020 | 22/09/2020 | Free |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): *See above.*   No | Peracetic acid (CAS-nr. 79-21-0) | Phago’Sanit  Phago’Spore  Phago’Wipes spore  [Full list of temporary authorisations](http://docs.health.belgium.be/COVID19/) delivered in the context of the fight against Covid-19 | PT 2 | Derogations granted to applicants  [Full list of authorisation holders for PT 2](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/07042020_liste_pt2_lutte_covid19.xlsx)  See [here](https://www.health.belgium.be/en/covid-19-temporary-authorisations#2) for details on obtaining derogations | 22/03/2020 | 18/09/2020 | Free |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): *See above.*   No | Propan-1-ol (CAS-nr 71-23-8) | Phytogel By HUCKERT'S sanitizer  [Full list of temporary authorisations](http://docs.health.belgium.be/COVID19/) delivered in the context of the fight against Covid-19 | PT 1 | Derogations granted to applicants  [Full list of authorisation holders for PT 1](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/07042020_liste_pt1_lutte_covid19.xlsx)  See [here](https://www.health.belgium.be/en/covid-19-temporary-authorisations#2) for details on obtaining derogations | 27/03/2020 | 23/09/2020 | Free |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): *See above.*   No | Propan-2-ol (CAS-nr 67-63-0) | Protectol® schützt (I)  [Full list of temporary authorisations](http://docs.health.belgium.be/COVID19/) delivered in the context of the fight against Covid-19 | PT 1 | Derogations granted to applicants  [Full list of authorisation holders for PT 1](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/07042020_liste_pt1_lutte_covid19.xlsx)  See [here](https://www.health.belgium.be/en/covid-19-temporary-authorisations#2) for details on obtaining derogations | 26/03/2020 | 22/09/2020 | Free |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): *See above.*   No | Propan-2-ol (CAS-nr. 67-63-0) | RADIA C 182  [Full list of temporary authorisations](http://docs.health.belgium.be/COVID19/) delivered in the context of the fight against Covid-19 | PT 1 | Derogations granted to applicants  [Full list of authorisation holders for PT 1](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/07042020_liste_pt1_lutte_covid19.xlsx)  See [here](https://www.health.belgium.be/en/covid-19-temporary-authorisations#2) for details on obtaining derogations | 22/03/2020 | 18/09/2020 | Free |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): *See above.*   No | Propan-2-ol (CAS-nr 67-63-0) | SOLUTION HYDROALCOOLIQUE  [Full list of temporary authorisations](http://docs.health.belgium.be/COVID19/) delivered in the context of the fight against Covid-19 | PT 1 | Derogations granted to applicants  [Full list of authorisation holders for PT 1](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/07042020_liste_pt1_lutte_covid19.xlsx)  See [here](https://www.health.belgium.be/en/covid-19-temporary-authorisations#2) for details on obtaining derogations | 01/04/2020 | 28/09/2020 | Free |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): *See above.*   No | Propan-2-ol (CAS-nr 67-63-0) | Solution hydroalcoolique désinfectante  [Full list of temporary authorisations](http://docs.health.belgium.be/COVID19/) delivered in the context of the fight against Covid-19 | PT 1 | Derogations granted to applicants  [Full list of authorisation holders for PT 1](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/07042020_liste_pt1_lutte_covid19.xlsx)  See [here](https://www.health.belgium.be/en/covid-19-temporary-authorisations#2) for details on obtaining derogations | 26/03/2020 | 22/09/2020 | Free |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): *See above.*   No | Propan-2-ol (CAS-nr 67-63-0) | Solution hydroalcoolique recommandée par l’Organisation  mondiale de la Santé pour l’antisepsie des mains  [Full list of temporary authorisations](http://docs.health.belgium.be/COVID19/) delivered in the context of the fight against Covid-19 | PT 1 | Derogations granted to applicants  [Full list of authorisation holders for PT 1](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/07042020_liste_pt1_lutte_covid19.xlsx)  See [here](https://www.health.belgium.be/en/covid-19-temporary-authorisations#2) for details on obtaining derogations | 29/03/2020 | 25/09/2020 | Free |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): See above.   No | Propan-2-ol (CAS-nr 67-63-0) | TueTous Alcogel  [Full list of temporary authorisations](http://docs.health.belgium.be/COVID19/) delivered in the context of the fight against Covid-19 | PT 1 | Derogations granted to applicants  [Full list of authorisation holders for PT 1](https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/07042020_liste_pt1_lutte_covid19.xlsx)  See [here](https://www.health.belgium.be/en/covid-19-temporary-authorisations#2) for details on obtaining derogations | 31/03/2020 | 27/09/2020 | Free |  |  |  |
| **Bulgaria** | **Article 55(1)?**  Yes   1. Notification: [Insert] 2. National law(s): [Insert]   No  [Insert] | WHO Formulation 1: Ethanol Glycerol Hydrogen peroxide | ANTIBAK / АНТИБАК | PT 1 | General public Professional users | 13/04/2020 | 10/10/2020 | 1890 BGN (circa € 1000) |  |  | Ministry of Health  State Health Control Directorate  [biocides@mh.government.bg](mailto:biocides@mh.government.bg)  +359 2 9301 214 |
|  | **Article 55(1)?**  Yes ☒☐  1. Notification:  [Insert]  2. National law(s):  [Insert]  No ☐  **[Insert]** | WHO Formulation 1: Ethanol Glycerol Hydrogen peroxide | Primasept / Примасепт | PT 1 | General public Professional users | 06/04/2020 | 03/10/2020 | 1890 BGN (circa € 1000) |  |  |  |
| **Croatia** | **Article 55(1)?**  Yes   1. Notification:   (in Croatian) *Nothing on circabc yet*.   1. National law(s): [Registration of biocidal products](https://zdravlje.gov.hr/djelokrug-1297/sanitarna-inspekcija/kemikalije-i-biocidni-pripravci-1357/biocidni-pripravci-1786/upis-biocidnih-pripravaka-u-registar-1862/1862)   No | Ethanol |  |  |  | 27/03/2020  *Publication date of the notification document* | 01/09/2020 |  | Proof of Article 95 listing not required and substance may be purchased from entities not listed on Article 95 List |  | Ministry of Health  [biocidi@miz.hr](mailto:biocidi@miz.hr)  +385 (1) 4607 555  Email address for application:  [ekologija@hzjz.hr](mailto:ekologija@hzjz.hr). |
| **Cyprus** | **Article 55(1)?**  Yes   1. Notification: [Insert] 2. National law(s): [Insert]   No  [Insert] |  |  |  |  |  |  |  |  |  | Ministry of Agriculture, Natural Resources and Environment - Department of Agriculture  [director@da.moa.gov.cy](mailto:director@da.moa.gov.cy)  +357 224 08 519 |
| **Czech Republic** | **Article 55(1)?**  Yes   1. Notification: [Insert] 2. National law(s): 3. [Insert]   No  [Insert] | Ethanol  Propan-2-ol | WHO formulations 1 and 2 | PT1 |  |  |  |  |  | Export restriction seems to be in place | Ministry of Health of the Czech Republic  Department of Strategy and Management of Public Health  [biocidy@mzcr.cz](mailto:biocidy@mzcr.cz)  +4202 6708 2305 |
| **Denmark** | **Article 55(1)?**  Yes   1. Notification:  * National law(s): [Hand Disinfectant](https://mst.dk/service/nyheder/nyhedsarkiv/2020/mar/vejledning-omkring-lovlig-markedsfoering-af-haandsprit-haanddesinfektionsmidler/) 17 March 2020   [Hand disinfectant 22 March 2020](https://mst.dk/service/nyheder/nyhedsarkiv/2020/mar/vejledning-omkring-lovlig-markedsfoering-af-haandsprit-og-haanddesinfektionsmidler/)[Hand sprays 23 March 2020](https://mfvm.dk/nyheder/nyhed/nyhed/miljoeministeren-giver-flere-virksomheder-mulighed-for-at-producere-haandsprit/)No | Propan-2-ol | TUNAP Hånddesinfektionsmiddel | PT 1 | All producers of hand sanitizer must still be registered in the Danish Product register or the The Danish Environmental Protection Agency. | 03/04/2020 | 30/06/2020 | Derogation based on earlier assessments DKK 2.500  Derogation under Article 55(1) DKK  238.000 | The Danish Environmental Protection Agency ("EPA") can derogate from the demand that active substance suppliers need to be on the article 95 list. Substance may be purchased from entities not listed on Article 95 List , but the Danish EPA must be informed at biocides@mst.dk if the active substance does not come from a supplier on ECHA's Article 95 list until 30. June |  | Danish Environmental Protection Agency (Miljøstyrelsen)  Ministry of Environment and Food of Denmark, the Department  [biocideshelpdesk@mst.dk](mailto:biocideshelpdesk@mst.dk)  +45 72 54 40 00  +45 22 34 95 89 |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): [Insert]   No | Tartaric acid, Lactic acid Lavender  oil, Peppermint oil | Uniblue UDF2/UDW2 | PT 2  PT 3  PT 4 |  | 03/04/2020 | 30/09/2020 |  |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): [Insert]   No | Propan-2-ol | WHO, formulation 2 | PT 1 |  | 23/03/2020 | 30/06/2020 |  |  |  |  |
| **Estonia** | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): [Insert]   No | Propan-2-ol | WHO Formulation 2 | PT 1 |  | 27/03/2020 | 01/05/2020 |  |  |  | Health Board  [biotsiid@terviseamet.ee](mailto:biotsiid@terviseamet.ee)  [KOOBiotsiid@terviseamet.ee](mailto:KOOBiotsiid@terviseamet.ee) |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): [Insert]   No | Ethanol | Biocide containing ethanol | PT 1  PT 2  PT 4 |  | 19/03/2020 | 01/05/2020 |  | *“In order to secure the supply of disinfection product a temporary exemption form the BPR Article 95 for the making available on the market and use of the disinfectants containing ethanol have been granted in Estonia”* Substance may be purchased from entities not listed on Article 95 List |  |  |
| **Finland** | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): [Insert] No | Hydrogen peroxide 3% | OxiskinPlus | PT 1  PT 2 | Products have to be registered in national register | 27/03/2020 | 23/09/2020 | During normal times, the basic the basis fee is € 3000 (but they are now working on a hourly rate) | No derogation from article 95, exceptionally substances may be purchased from entities not listed on Article 95 List until 31.7.2020, because of Coronavirus pandemia |  | Finnish Safety and Chemicals Agency (TUKES)  [ca\_biocides@tukes.fi](mailto:ca_biocides@tukes.fi)  +358 50 597 6338 |
| **France** | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): [Arrêté du 20 mars 2020](https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000041741016&categorieLien=id) (modifying [Arrêté du 13 mars 2020](https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000041721724&categorieLien=id)) and [Arrêté du 6 mars 2020](https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000041697126&fastPos=9&fastReqId=579322875&categorieLien=cid&oldAction=rechTexte) (all in *French*)   No | Ethanol, Propan-2-ol | 3 products containing ethanol (WHO  formulation as well as 2 additional  formulations discussed with  manufacturers)  1 product containing isopropanol  (WHO formulation) | PT 1 | Pharmacies: WHO Formulation I;  Industrial facilities (cosmetic and biocidal industries and installations classified for environmental protection subject to authorisation or registration): WHO Formulations I-II and or a fourth (ethanol based) | 06/03/2020 | 31/05/2020 |  | Substance may be purchased from entities not listed on Article 95 List, but the derogations contain source-specifications (see: Arrêté du 20 mars 2020) |  | Ministère de l'écologie, du développement durable et de l'énergie  [biocides@developpement-durable.gouv.fr](mailto:biocides@developpement-durable.gouv.fr)  +33(0)140 81 87 00 |
| **Germany** | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): Allgemeinverfühung vom 04.03.2020 (in *German*)   No | Propan-2-ol | WHO Formulation 2; 70% (v/v)  Propan-2-ol in aqueous solution | PT 1 | Only pharmacies and pharmaceutical industry | 04/03/2020 | 31/08/2020 |  | Substance may be purchased from entities not listed on Article 95 List (see [German FAQs](https://www.baua.de/DE/Themen/Anwendungssichere-Chemikalien-und-Produkte/Chemikalienrecht/Biozide/FAQ/FAQ_node.html) in *German*) | Importers need to be part of chemical / pharmaceutical industry (see [German FAQs](https://www.baua.de/DE/Themen/Anwendungssichere-Chemikalien-und-Produkte/Chemikalienrecht/Biozide/FAQ/FAQ_node.html) in *German*) | Bundesanstalt für Arbeitsschutz und Arbeitsmedizin Bundesstelle Chemikalien / Zulassung Biozide (Federal Institute for Occupational Safety and Health)  [chemg@baua.bund.de](mailto:chemg@baua.bund.de)  +49 231 9071 2443  +49 231 9071 2326  +49 231 9071 2518 |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): Allgemeinverfügung vom 20.03.2020 wird durch Allgemeinverfügung vom 09. April aktualisiert   **Aktenzeichen** 5.0- 710 30/01.00003 (Fassung vom 15.April 2020)  (in *German*)  No | Propan-2-ol; Propan-1-ol; Ethanol | Products for hygienic hand  disinfection | PT 1 | Pharmacies, pharmaceutical and chemical industry and legal entities under public law, only to be distributed to professional users  (specific rules and conditions apply for ethanol) | 13/03/2020 | 06/10/2020 |  | See above. | See above. |  |
|  | **Article 55(1)?**  Yes   1. Notification: *Nothing on circabc yet* 2. National law(s): [Allgemeinverfügung vom 02.04.2020](https://www.baua.de/DE/Angebote/Aktuelles/Meldungen/2020/pdf/Allgemeinverfuegung-Oberflaechen.pdf?__blob=publicationFile&v=3) (in *German*)   No | Ethanol; Natriumhypochlorit; Chloramin-T | Surface disinfection | PT 2 | Use by professional users  (specific rules and conditions apply for ethanol) | 02/04/2020 | 30/09/2020 |  | See above. | See above. |  |
|  | **Article 55(1)?**  Yes ☒  1.Notification:  2.National law(s):  No ☐ | Other ethanol based | Disinfection |  | Specific rules and conditions apply for ethanol, for conditions see [German FAQs](https://www.baua.de/DE/Themen/Anwendungssichere-Chemikalien-und-Produkte/Chemikalienrecht/Biozide/FAQ/FAQ_node.html) (in *German*) | [Insert] | [Insert] |  |  |  |  |
|  | **Article 55(1)?**  Yes ☒  1.Notification:    2.National law(s):  No ☐ | 2,2’ - (1-methyltrimethylenedioxy)bis - (4-methyl-1, 3, 2- dioxaborinane) (CAS-Nr.: 2665-13- 6) and  2. 2,2’ - oxybis (4, 4, 6 - trimethyl1,3, 2-dioxaborinane) (CAS-Nr.: 14697-50-8) | Biobor JF | PT 6 | Professional | 07/04/2020 | 04/10/2020 |  |  |  |  |
| **Greece** | **Article 55(1)?**  Yes   1. Notification: [Insert] 2. National law(s): A ministerial decree issued on 24/3   No  [Insert] |  | According to WHO specifications | PT 1 | pharmaceutical and cosmetic industries |  |  |  | Derogation foreseen  Substance may be purchased from entities not listed on Article 95 List | Imports of alcohols ex third countries is permitted  Only for ethanol imports | Ministry of Rural Development and Food General Directorate of Plant Produce  [syg057@minagric.gr](mailto:syg057@minagric.gr)  [elhelpdesk@gcsl.gr](mailto:elhelpdesk@gcsl.gr)  biocides@eof.gr  +30 210 928 72 19+30 210 64 79 286  +30 210 64 79 287  +30 213 2040 200 |
| **Hungary** | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): [Insert]   No  [Insert] | Ethanol, Propan-2-ol, Sodium hypochlorite, ADBAC, DDAC, glutaraldehyde | According to WHO specifications  WHO formulations, products in line with ECDC recommendationsand production permits for previously authorised formulations under the scope of transitional measures | PT 1  PT 2 | General public, professional, industrial | 16/03/2020 | 31/08/2020 |  |  |  | National Public Health Center,  Department for Chemical Safety and Competent Authorities  [biocide.authority@nnk.gov.hu](mailto:biocide.authority@nnk.gov.hu)  [biocide.helpdesk@nnk.gov.hu](mailto:biocide.helpdesk@nnk.gov.hu)  [tisztifoorvos@nnk.gov.hu](mailto:tisztifoorvos@nnk.gov.hu)  kembizt@nnk.gov.hu  +36 1 476 1100 |
| **Ireland** | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): [Insert]   No | Propan-1-ol, propan-2-ol | Propan-1-ol and propan-2-ol  containing products | PT 1 | Individual application for derogation necessary | 20/03/2020 | 16/09/2020 | €300 |  |  | Pesticide Registration and Control Divisions  Department of Agriculture, Food and the Marine  [Biocide-Authorisations@agriculture.gov.ie](mailto:Biocide-Authorisations@agriculture.gov.ie)  +353 1 615 7552 |
| **Italy** | **Article 55(1)?**  Yes  No  National laws:  [”Presidi Medico-Chirurgici” (PMC](https://www.iss.it/documents/20126/0/LINEA_GUIDA_PMC_MINISTERO.pdf/9ff17dc3-ad2b-2049-e556-d8960205e2d0?t=1584962373070)) of 19 March 2020 (also see [Authorization procedures for the Marketing and Production of Disinfectant Products in Italy by Ministero della Salute](http://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2020&codLeg=73819&parte=2&serie)) | Active substances currently under evaluation (not yet approved) | All products that claim a disinfectant, bactericidal, virucidal action or any action able to fight microorganisms | PT 1  PT 2 | Individual application for derogation necessary, submitting documents relating to:  - active substance supplier,  - product  efficacy study (EN 14476)[[1]](#footnote-1),  - technical data sheet,  - full composition and product label proposal that  will show the following indication:"Exemption authorization pursuant to art. 55.1 BPR "  Submission to be made to:  [dgfdm@postacert.sanita.it](mailto:dgfdm@postacert.sanita.it) or to the helpdesk at: [biocidi@sanita.it](mailto:biocidi@sanita.it) , with  indication of the object: “Covid Emergency-19 - Request for authorization in derogation pursuant to art. 55 BPR” |  |  | Fees applicable, [Insert] | Substance may **not** be purchased from entities not listed on Article 95 List |  | Istituto Superiore di Sanità  [segreteria.biocidi@iss.it](mailto:segreteria.biocidi@iss.it)  +39 06 4990 3192  According to the Commission Notification:  Ministero della salute  Direzione generale dei dispositivi medici e del servizio farmaceutico  [dgfdm@postacert.sanita.it](mailto:dgfdm@postacert.sanita.it)  [biocidi@sanita.it](mailto:biocidi@sanita.it) |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): see above   No | Propan-1-ol; Propan-2-ol | HOLLUDES PROMANO GEL | PT 1 | Derogations granted to applicants | 08/04/2020 | 05/10/2020 |  |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): see above 3. No | Propan-1-ol; Propan-2-ol | HOLLUDES PROMANO MED | PT1 | Derogations granted to applicants | 08/04/2020 | 05/10/2020 |  |  |  |  |
|  | **Article 55(1)?**  Yes ☒☐  1. Notification:  [Insert]  2. National law(s): see above | Propan-2-ol Hydrogen peroxide | Preparato disinfettante ad azione antimicrobica per frizione igienica delle mani (i.e. hands disinfectant) | PT 1 | Professional | 15/04/2020 | 12/10/2020 | Free |  |  |  |
| **Latvia** | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): Order of Latvian Environment Geology and Meteorology Centre (LEGMC) of 19 March 2020   No | Ethanol | WHO I Formulation | PT 1 | Pharmacies only | 19/03/2020 | 14/09/2020 |  | Substance may **not** be purchased from entities not listed on Article 95 List |  | Latvian Environment, Geology and Meteorology Centre  [biocides@lvgmc.lv](mailto:biocides@lvgmc.lv)  +371 67 032 600 |
| **Lithuania** | **Article 55(1)?**  Yes   1. Notification: *Nothing on circabc yet* [Insert] 2. National law(s): [Insert]   No  [Insert] | Ethanol | WHO Formulation I | PT 1 |  |  |  |  |  |  | Vilnius Public Health Centre Public health safety division Biocides and chemicals evaluation subdivision  [info@nvsc.lt](mailto:info@nvsc.lt)  +370 5 212 4098 |
| **Luxembourg** | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): [Insert]   No | Ethanol  Propan-2-ol | WHO Formulation I and II | PT 1 | Distribution of products only through pharmacies | 26/03/2020 | 15/09/2020 |  |  |  | Administration de l'environnement Unité substances chimiques et produits Biocides  [biocides@aev.etat.lu](mailto:biocides@aev.etat.lu)  +352 40 56 56 300 |
|  | **Article 55(1)?**  Yes ☒  1. Notification:    2. National law(s):  [Insert]  No ☐ | Ethanol | WHO Formulation I  Difrulux- formulation 6075  Difrulux- WHO Typ I formulation  Difrulux- formulation 6098875 | PT 1 | General public Professional user | 06/04/2020 | 03/10/2020 |  |  |  |  |
|  | **Article 55(1)?**  Yes ☒  1. Notification:    2. National law(s):  [Insert]  No ☐ | Ethanol | WHO Formulation I  Robhydral L-28464 | PT 1 | General public Professional user | 09/04/2020 | 06/10/2020 |  |  |  |  |
|  | **Article 55(1)?**  Yes ☒  1. Notification:    2. National law(s):  [Insert]  No ☐ | Ethanol  Propan-2-ol | WHO Formulation II  Robhydral L-28460 | PT 1 | General public Professional user | 09/04/2020 | 06/10/2020 |  |  |  |  |
| **Malta** | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): [Insert]   No | Ethanol, Propan-2-ole | Handex Hand Sanitizer Refreshing Gel | PT 1 | Alcohol based products which do not contain impurities or components classified as carcinogenic category 1. | 15/03/2020 | 15/06/2020 | €100 | Substance may **not** be purchased from entities not listed on Article 95 List |  | Malta Competition and Consumer Affairs Authority  [biocides@mccaa.org.mt](mailto:biocides@mccaa.org.mt)  +356 2395 2000 |
| **Netherlands** | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): [Tijdelijke vrijstelling handdesinfectie WHO-formuleringen COVID-19 2020](https://wetten.overheid.nl/BWBR0043285/2020-03-20) (in *Dutch*)   No | Ethanol  Glycerol  Propan-2-ol | Products for hand disinfection | PT 1 | Formulated by the Laboratory of  Pharmacists in The Netherlands  (LNA) and only to be distributed to and used by professional users in the healthcare sector | 10/03/2020 | 05/09/2020 |  |  |  | College voor de toelating van Gewasbeschermingsmiddelen en Biociden - CtGB  [biocides@ctgb.nl](mailto:biocides@ctgb.nl)  +31 317 471 810  Contact details in Article 55(1) notification:  Ministry of Infrastructure and Water Management (RIVM)  Biociden\_NL@minienw.nl |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): [Insert]   No | Products with at least one of the  following active substances:  • Alcohols (minimum 70%);  • Hydrogen peroxide  (minimum 0,5%); and  • Sodium Hypochlorite  (minimum 0,1%). | Products authorised under Dutch  National Law or the BPR, for hygienic hand disinfection (without a virucidal claim) | PT 1 | Formulated by the Laboratory of  Pharmacists in The Netherlands  (LNA) | 14/03/2020 | 09/09/2020 |  |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): [Insert]   No | Biocides contain at least one of the  following substances:  • Alcohols (minimum 70%);  • Sodium Hypochlorite  (minimum 0,025% active  Chlorine); and  • Sodium Dichloro  Isocyanurate  (in a user concentration of  minimum 1.000 ppm active  Chlorine). | Products authorised under Dutch  National Law or the BPR, without a  virucidal claim, for disinfection of  surfaces in healthcare, cosmetic or  pharmaceutical industry or for use  in spaces for human residence. | PT 2 | For professional healthcare only | 25/03/2020 | 20/09/2020 |  |  |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): see above   No | Formulation 1:  Ethanol  Glycerol  Hydrogen peroxide  Formulation 2:  Propan-2-ol  Glycerol  Hydrogen peroxide | WHO-recommended formulations  for hygienic hand disinfection  (formulations Ethanol and Propan2-ol) | PT 1 | For professional healthcare only | 17/03/2020 | 10/09/2020 |  |  |  |  |
|  | **Article 55(1)?**  Yes ☒  1. Notification:    2. National law(s):  [Insert]  No ☐ | The disinfectants contain at least one of the following active substances Ethanol Propan-1-olPropan-2-ol Hydroxen peroxide (only PT1) Sodium hypochlorite Sodium dichloro isocyanurate (only PT2) | Products for disinfection that are authorized to the Dutch market under Dutch National Law, the BPR (except for Union Authorisations) against viruses (including SARSCoV-2), for the disinfection of hands (PT1) or surfaces in the healthcare sector (PT2), and the products that are temporarily released for the disinfection of hands and surfaces in the health care sector under the Temporary exemptions for hand disinfection and the disinfection surfaces | PT 1  PT 2 | Professional user in healthcare | 03/04/2020 | 29/09/2020 |  |  |  |  |
| **Poland** | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): [Registration under national procedure](http://www.urpl.gov.pl/en/biocidal-products/biocidal-products-registration/registration-under-national-procedure)   No | Ethanol  Propan-2-ol  Combination of active substances | Biocides with the active  substances | PT 1  PT 2  PT 4 |  | 10/03/2020 | 31/10/2020 |  |  | Export restriction seems to be in place | Office for Registration of Medicinal Products, Medical Devices and Biocidal Products  Biocidal Products Assessment Unit  [biocides@urpl.gov.pl](mailto:biocides@urpl.gov.pl)  [pb@urpl.gov.pl](mailto:pb@urpl.gov.pl)  +48 22 49 20 900 |
| **Portugal** | **Article 55(1)?**  Yes   1. Notification: *Nothing on circabc yet* 2. National law(s): [Insert]   No  [Insert] | Approved active substances: isopropanol, Propan-1-ol, sodium hypochlorite |  | PT 1, 2, 3 | Existing notifications (before approval of the active substances) remain valid until potential centralization of the applications at EU level.  Companies that did not submit previous notification will have to apply for an authorization in accordance with article 55(1).. |  |  |  |  |  | Direção-Geral da Saúde (DGS)  [geral@dgs.pt](mailto:geral@dgs.pt)  +351 218 430 500 |
|  |  | Active substances not yet approved at European level (e.g.: ethanol) | Disinfectant biocidal products | TP1, 2, 4 | For this kind of products, the national rules oblige companies to notify the authorities, which is a simpler procedure (when compared to BPR authorizations). In normal situations, these notifications are submitted to the Authorities in a paper format, with certified signature and sent by registered mail. During this period of crisis, as a derogation from this normal procedure, the authorities accept these notifications by e-mail. |  |  |  |  |  |  |
| **Romania** | **Article 55(1)?**  Yes   1. Notification: *Nothing on circabc yet* 2. National law(s): Article 10 of Military Ordinance no. 4   No |  |  |  | Only punctually to biocidal industries that have a solid experience |  |  |  |  | Export restriction seems to be in place [Insert] | Ministry of Health  National Committee for Biocidal Products  [biocide@insp.gov.ro](mailto:biocide@insp.gov.ro)  +40 21 311 86 20  Information from Ministry*:*  *'Article 10 - (1) during the state of emergency, the Center for Medical-Military Scientific Research, the Center for Scientific Research on Defense, CBRN1 and Ecology, the Research Agency for Military Technical and Technology and the national Institute for Research on Medical-Military Development "Cantacuzino" shall be authorized for the approval/authorization of materials, components, Medical equipment and devices necessary for the prevention and control of spread, as well as for the treatment of SAR-CoV-2 virus infection and biocids respectively.’* |
| **Slovak Republic** | **Article 55(1)?**  Yes   1. Notification: *no pdf available yet* 2. National law(s): [Insert]   No  [Insert] | Ethanol  Isopropanol  Peracetic acid  Hydrogen peroxide | Klercide 70/30 IPA  Klercide Sporicidal Low Residue Peroxide  Klercide Sporicidal Enhanced Peroxide  INCIDIN OXYFOAM S  DrySan Oxy  Ozonit Super  Ozonit PERformance  Hyg-dez surface  Fortea VIRUS KILLER  Lactosan HPX 2,5%  DusIPA  DusIPA G  DEZIX Dezinfekčný prípravok na ruky s izopropylalkoholom  CHLÓRNAN SODNÝ C19 | 1, 2, 4 | Obligation to collect and keep records of sale volumes, customer identifications etc. in the whole supply chain, lies with the decision holder |  |  | free | Article 95 applies |  | Ministry of Economy of the Slovak Republic  Centre for Chemical Substances and Preparations  Biocides Unit  [biocides@mhsr.sk](mailto:biocides@mhsr.sk)  +4212 4854 4513  +421 907 957 583 |
| **Slovenia** | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): [Insert]   No | Propan-2-ol,  Hydrogen peroxide  Propan-2-ol | HAND SANITIZER  STELLA izopropilni alkohol 70 % | PT 1  PT 2 | PT1 for use in health and other institutions by professional users  PT 2 for use by general public and professional users | 30/03/2020 | 26/09/2020 |  | Substance may be purchased from entities not listed on Article 95 List |  | Chemicals Office of the Republic of Slovenia, Ministry of Health  [gp-ursk.mz@gov.si](mailto:gp-ursk.mz@gov.si)  +386 1 400 6051 |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): [Insert]   No | Propan-2-ol | 70% Izopropanol | PT 2 | Derogation granted to one pharmaceutical company to donate product for use in health and other public institutions, in units of Armed Forces, Policy and Administration and economic operators. | 26/03/2020 | 22/09/2020 |  |  |  |  |
| **Spain** | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): [Real Decreto 463/2020](http://noticias.juridicas.com/base_datos/Laboral/661797-rd-463-2020-de-14-mar-estado-de-alarma-para-la-gestion-de-la-situacion-de.html#a4) and [Notice to producers of 24 March 2020](https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov-China/documentos/Proveedores_fabricantes_biocidas.pdf) (both in *Spanish*)   No | - Propan-1-ol  - Propan-2-ol | Biocides containing the active  substances. | PT 1  PT 2  PT 4 | Non-professional user (general public) Professional user Trained professional  - | 24/03/2020 | 24/09/2020 |  | Derogation from Article 95 in place. Substance may be purchased from entities not listed on Article 95 List, but sources have to be notified to the authorities  Information to submitted to the authority: the commercial name of the product, composition, information on safety requirements, contact information of the firm, registration number of the product in other member states where they are commercialized, purity of active substance, identification of relevant impurities and method of analysis for a.s.  If a dossier has been already submitted for national authorization, the Spanish authority does not allow to switch the claim to Article 55(1) BPR.  Authorities claim the lack of a fast track procedure for surface disinfectants |  | Ministry of Health  [sgsasl@mscbs.es](mailto:sgsasl@mscbs.es)  +34 91 5962085 |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): the above Real Decreto and [Notice to producers of 31 March 2020](https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov-China/documentos/Tercera_nota_informativa_para_proveedores_y_fabricantes_de_biocidas.pdf)   No | Active chlorine released  from sodium hypochlorite  (CAS number: 7681-52-9) | Biocides containing the active  substances | PT 2  PT 4 | Non-professional user (general public) Professional user Trained professional | 31/03/2020 | 01/10/2020 |  | See above |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: *Nothing on circabc yet* 2. National law(s): [the](http://noticias.juridicas.com/base_datos/Laboral/661797-rd-463-2020-de-14-mar-estado-de-alarma-para-la-gestion-de-la-situacion-de.html#a4) above Real Decreto and [Notice to producers of 27 March 2020](https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov-China/documentos/proveedoresDeterminadasSustanciasBiocidas2.pdf) (both in *Spanish*)   No | Concerns active substances undergoing evaluation:  -Cloruro de C12-16-alquildimetilbencilamonio (ADBAC/BKC (C12-16))  -Cloruro de C12-18-alquildimetilbencilamonio (ADBAC (C12-18))  -Cloruro de C12-14-alquildimetilbencilamonio (ADBAC (C12-14))  -Cloruro de C12-14-alquiletilbencilamonio (ADEBAC (C12-14))  -Cloruro de didecildimetilamonio (DDAC (C8-10))  -Cloruro de didecildimetilamonio (DDAC)  -Cloruro de dimetiloctadecil[3-(trimetoxisilil)propil]amonio |  | PT 2, 4 |  |  |  |  | See above |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: *Nothing on circabc yet*   No   1. National law(s):   [Procedural instructions for TP1 products containing ethanol](https://www.aemps.gob.es/cosmeticos-cuidado-personal/docs/Instrucciones-autorizacion-excepcional-antisepticos-piel-sana-COVID-19.pdf?x33378) (in *Spanish*) | Ethanol |  | TP1 | Only applies to producers that had been previously authorized to commercialize products containing ethanol before.  . |  |  |  | Producers should, after the payment of a fee, submit to the AEMPS at [biocidas-aemps@aemps.es](mailto:biocidas-aemps@aemps.es), an application containing the data listed [here](https://www.aemps.gob.es/informa/notasinformativas/cosmeticoshigiene/biocidas/2020-biocidas/la-aemps-establece-medidas-excepcionales-para-agilizar-las-autorizaciones-de-productos-antisepticos-de-piel-sana/).  The authorizations are granted for three months and producers can request an extension within 15 days before the expiry date. |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: *Nothing on circabc yet*   No   1. National law(s):   [Orden SND/321/2020, de 3 de abril](https://www.boe.es/boe/dias/2020/04/04/pdfs/BOE-A-2020-4294.pdf) (in *Spanish*) | Use of bioethanol in the composition of such products for a period corresponding to the implementation period of Royal Decree 463/2020.  For such uses, the bioethanol must comply with the following conditions:  – Metanol < 200 ppm (V/V).  – Acetaldehído < 10 ppm (V/V).  – Benceno < 2 ppm (V/V).  – Total, de otras impurezas < 300 ppm.  The total mix of carcinogenic components must be <0,1%. | Hand disinfectant | PT 1 |  |  |  |  |  |  |  |
| **Sweden** | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): [Beslut om dispens 20 March 2020](https://www.kemi.se/files/a8f6be106eb14cbbb3f69274e3dc7b26/beslut-om-dispens-desinfektionsmedel-2020-03-20.pdf)  (in *Swedish)*   No | Propan-1-ol Propan-2-ol | Disinfectants containing 1- or 2-  propanol | PT 1-4 | Sale to general public only though pharmacies or grocery stores | 20/03/2020 | 16/09/2020 | SEK 15.000 (around EUR 1.347) | Until 30 June, the Swedish Chemicals Agency accepts manufacturing and selling of disinfectants without the suppliers being on the Article 95 List  Until the 30 April, the Swedish Chemicals Agency accepts labelling also in English, Danish, and Norwegian |  | Swedish Chemicals Agency  [kemi@kemi.se](mailto:kemi@kemi.se)  +46 8 519 41100 |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): [Beslut om dispens 20](https://www.kemi.se/files/67235c3331e744daaa0fc6c08f206638/beslut-om-dispens-desinfektionmedel-h20-04458.pdf) March 2020   No | Active chlorine generated from  sodium chloride by electrolysis  Active chlorine released from  hypochlorous acid | Disinfectants containing  - Active chlorine generated  from sodium chloride by  electrolysis  or  - Active chlorine released from hypochlorous acid | PT 1 | Sale to general public only though pharmacies or grocery stores | 20/03/2020 | 16/09/2020 | SEK 15.000 (around EUR 1.347) | See above |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): [Beslut om dispens 20](https://www.kemi.se/files/67235c3331e744daaa0fc6c08f206638/beslut-om-dispens-desinfektionmedel-h20-04495.pdf) March 2020   No | -Hydrogen Peroxide  -Active chlorine released  from sodium hypochlorite | Disinfectants containing  - Hydrogen Peroxide  or  - Active chlorine released  from sodium hypochlorite | PT 1-4 | Sale to general public only though pharmacies or grocery stores | 23/03/2020 | 19/09/2020 | SEK 15.000 (around EUR 1.347) | See above |  |  |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s):   No   See [KEMI FAQ](https://www.kemi.se/en/pesticides-and-biocides/biocidal-products/rules-for-common-types-of-biocidal-products/frequently-asked-questions-regarding-disinfectants-and-the-coronavirus) | Ethanol |  |  |  |  |  | SEK 15.000 (around EUR 1.347) | See above |  |  |
| **United Kingdom** | **Article 55(1)?**  Yes   1. Notification: 2. National law(s):   No  Also see [HSE FAQ](https://www.hse.gov.uk/news/hand-sanitiser-manufacture-supply-coronavirus.htm) | Ethanol: Transitional rules, no authorization required (see [HSE FAQ](https://www.hse.gov.uk/news/hand-sanitiser-manufacture-supply-coronavirus.htm)) |  |  |  |  |  |  | HSE will adopt a pragmatic and proportionate approach to regulatory requirements that relate to supply chain obligations during this period. The focus of any HSE activity by inspectors will be to ensure that products on the market are effective in combating the coronavirus and do not pose an unacceptable risk to people or the environment.  HSE expects product manufacturers to take all reasonable steps to source ingredients in such a way that compliest with Article 95 obligations.  However, HSE Inspectors will take a sensible and proportionate approach if they come across hand sanitisers that are not strictly in line with normal BPR supply chain requirements under Article 95, recognising the urgent wider need for safe and effective products.  In making commercial decisions, manufacturers need to be mindful of maintaining high levels of safety and efficacy of the products they make available to the public and others. |  | Health and Safety Executive (HSE)  [pa.biocides@hse.gov.uk](mailto:pa.biocides@hse.gov.uk) |
|  | **Article 55(1)?**  Yes   1. Notification: 2. National law(s): [Insert]   Also see [HSE FAQ](https://www.hse.gov.uk/news/hand-sanitiser-manufacture-supply-coronavirus.htm)  No | Propan-2-ol | WHO-recommended handrub Formulation 2 (Propan-2-ol) | PT 1 | Companies must notify HSE to obtain derogation certificate:  [biocidesenquiries@hse.gov.uk](mailto:biocidesenquiries@hse.gov.uk) using ‘Propan-2-ol Article 55’ as the subject title | 30/03/2020 | 25/09/2020 |  | See above. |  |  |
| **Non-EU Member States** | | | | | | | | | | | |
| **Iceland (EEA)** | **Article 55(1)?**  Yes   1. Notification: [Insert] 2. National law(s): [Insert]   No  [Insert] |  |  |  |  |  |  | EUR 500 |  |  | Environment and Food Agency of Iceland  [ust@ust.is](mailto:ust@ust.is)  +354 591 2000 |
| **Liechtenstein (EEA)** | **Article 55(1)?**  Yes   1. Notification: [Insert] 2. National law(s): [Insert]   No  [Insert] |  |  |  |  |  |  |  |  |  |  |
| **Norway (EEA)** | **Article 55(1)?**  Yes   1. Notification: [Insert] 2. National law(s): [Insert]   No  [Insert] | Norway is currently considering certain general derogations for disinfectants in PT 1,2 and 4 containing ethanol, propan-1-ol og propan-2-ol. They will update our webpages with further information as soon as a formal decision is made. |  |  |  |  |  |  |  |  | Norwegian Environment Agency  [biocides@miljodir.no](mailto:biocides@miljodir.no)  +47 735 80500 |
| **Switzerland(EFTA)** | 1. National law(s): [Ordinance 1](https://www.admin.ch/opc/en/classified-compilation/20021524/index.html#a30) August 2005 and   [Décision 28](https://www.admin.ch/opc/fr/federal-gazette/2020/1495.pdf) February 2020 | 70 à 80 % d’éthanol [No CAS 64-17-5], ou  – 60 à 80 % de 1-propanol [No CAS 71-23-8], ou  – 60 à 80 % de 2-propanol [No CAS Nr. 67-63-0], ou  – 60 à 80 % d’un mélange des alcools précités, et  – ≤ 0,5 % d’autres adjuvants tels que parfum, colorants ou glycérine, et  – ≤ 2 % de méthyléthylcétone, ou  – ≤ 5 % de 2-propanol comme agent dénaturant, et  – x %3 d’eau. |  | PT 1, 2, 4 |  |  | 31/08/2020 |  | Derogation from Article 95 possible. Substance may be purchased from entities not listed on Article 95 List, but need to be notified to authorities (authorization certificate will be issued if agreed) |  | Notification Authority for Chemicals  [cheminfo@bag.admin.ch](mailto:cheminfo@bag.admin.ch)  +41 58 462 73 05 |
| **Montenegro (Candidate)** | 1. National law(s): [Insert] |  |  |  |  |  |  |  |  |  |  |
| **Turkey (Candidate)** | 1. National law(s): Turkish Ministry of Health, 23th March 2020 and new regulation or amendment to dated 31.12.2009/ 27449 numbered official gazette as well as Art 15 of Turkish Biocidal regulation. Decree (dated 19.3.2020).   Issues a 3-months-valid transitional approval certificate (stability and efficiency tests must be submitted within 1 month otherwise this approval will be revoked).  Authorities implemented an accelerated registration program for disinfectant, hygienic and antibacterial cleaners.  Formerly, registration took min. 6 months while it is now provided in 2 to 3 weeks (but the related authorizations are valid for 3 months)  In Turkey there is not the opportunity to use non-approved ingredients in the formulation. |  |  |  |  |  |  |  |  |  |  |

1. It is not necessary to submit efficacy study in case of: (i) products with composition similar to the formulations recommended by ECDC and/or WHO; (ii) products already authorized in other Member States and for which virucidal efficacy has been assessed (provide a copy of product authorization granted by a Member State that assessed the product efficacy) (iii) products for which efficacy can be deduced by the composition (provide justification) [↑](#footnote-ref-1)