

**NOTIFICATION OF DEROGATION PURSUANT TO ARTICLE 55(1) OF REGULATION (EU) NO 528/2012**

- Notifying Member State<sup>1</sup>

Spain
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- Competent Authority granting the temporary derogation

Organisation	Email address
Ministry of Health	<a href="mailto:sgsasl@mscbs.es">sgsasl@mscbs.es</a>

- In case of repeated action: number of previous action(s)

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- Product name

<p>A. Biocidal products listed below, and/or their new suppliers of the active substances propan-1-ol and/or propan-2-ol:</p> <ol style="list-style-type: none"> <li>1. 880 (PT1)</li> <li>2. Abc hidroalcohólico (PT 1,2 and 4)</li> <li>3. Actrini clinic (PT1, 2, and 4)</li> <li>4. Alcocean (PT1)</li> <li>5. Alcoclean + lanaclean hidroalcoholico desinfectante (PT1, 2 and 4)</li> <li>6. Alcofresh (PT 1,2 and 4)</li> <li>7. Alcohol gel (PT1)</li> <li>8. Alcohol gel limpieza de las manos sin agua con glicerina (PT1)</li> <li>9. Alcohol isopropilico desinfectante prinex (PT2)</li> <li>10. Alergreen plus oms desinfectante (PT 1,2 and 4)</li> <li>11. Asepcol who (PT 2 and 4)</li> <li>12. Asepkol (PT 1,2 and 4)</li> <li>13. Bacclinic pro (PT2)</li> <li>14. Bact clean manos (PT 1,2 and 4)</li> <li>15. Bacter KL1N (PT2 and 4)</li> <li>16. Bactersan (PT1, 2, and 4)</li> <li>17. Bacti plus (PT 1,2 and 4)</li> <li>18. Baktogel plus (PT 1,2 and 4)</li> <li>19. Bamboo virus free (PT 1,2 and 4)</li> <li>20. Basf arcoiris (ipa) (PT1)</li> <li>21. Be hands clean (PT1)</li> <li>22. Betsan ip (PT 2 y 4)</li> <li>23. Biobacter 75 (PT 1,2 and 4)</li> </ol>
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<sup>1</sup> In this form "Member State" refers to EU Member States, Iceland, Liechtenstein, Norway and Switzerland.

24. Biohands ISP
25. Biomar gel hidroalcoholico para manos Rogemar (PT1, 2 and 4)
26. Caflon hsw2 (PT1)
27. Calgonit des-h (PT1)
28. Cesarol-147 (PT1)
29. CleanSanyt Desinfectante tejidos (PT2)
30. CleanSanyt Desinfectante manos (PT1)
31. CleanSanyt Desinfectante multiusos (PT1, 2, and 4)
32. CleanSanyt Desinfectante superficies (PT2 and 4)
33. Cleanser 320. Hcov desinfectante de superficies (PT 1,2 and 4)
34. Clear higienizante (PT 2 and 4)
35. CN-170/M (PT1)
36. CN-170/S (PT2 and 4)
37. Colsanit (PT1, 2, and 4)
38. Cpq dermonet® v19 (PT 1,2 and 4)
39. Crystalcare gel hidroalcoholico (PT 1,2 and 4)
40. Dar-adygel (PT2 and 4)
41. Dc ipaclean 70 (PT1)
42. Desfi-OMS (PT1, 2 and 4)
43. Desin\_4eco (PT 1,2 and 4)
44. Desinfect 75 (PT 1,2 and 4)
45. Desinfectante manos clean bmd (PT1)
46. Desinfectante manos clean prisma (PT1)
47. Desinfectante superficies clean bmd (PT2 and 4)
48. Desinfectante 75 % hidroalcohólico plis (PT1)
49. Desinfectante 75% hidroalcohólico (PT1, 2 and 4)
50. Desinfectante 75% hidroalcohólico actia care (PT1)
51. Desinfectante 75% hidroalcohólico actia care superficie (PT2 and 4)
52. Desinfectante 75% hidroalcohólico para manos (PT1)
53. Desinfectante 75% hidroalcohólico para superficies (PT2)
54. Desinfectante 75% hidroalcohólico para superficies en contacto con alimentos (PT4)
55. Desinfectante 75% hidroalcohólico para tejidos (PT2)
56. Desinfectante bactericida virucida manos (PT1)
57. Desinfectante bactericida virucida superficies (PT2 and 4)
58. Desinfectante bactericida virucida textil (PT2 and 4)
59. Desinfectante cocinas action 10 (PT 2 and 4)
60. Desinfectante DD4161 (PT1, 2 and 4)
61. Desinfectante de manos who formulación 2 (PT1)
62. Desinfectante de superficies kinefis (PT2)
63. Desinfectante de superficies vitale (PT2)
64. Desinfectante del medio ambiente 400 ml ambro-sol (PT2)
65. Desinfectante habitáculos monodosis one-shot 100 ml aerosol (PT2)
66. Desinfectante hidroalcoholico superficies action 10 (PT 2 and 4)

67. Desinfectante Hidroalcohólico Superficies Multiusos CERADI (PT 1,2 and 4)
68. Desinfectante inecoa (PT 1,2 and 4)
69. Desinfectante multiusos action 10 (PT 2 and 4)
70. Desinfectante para manos oms2 (PT1)
71. Desinfectante para superficies 400 ml ambro-sol (PT2)
72. Desinfectante stoptox (PT 1,2 and 4)
73. Desinfectante superficies clean prisma (PT2 and 4)
74. Desinfectool (PT1, 2 y 4)
75. Desinpro – oms (PT 1,2 and 4)
76. Diflomar pugna xxi (PT 1,2 and 4)
77. Disolim – ag (PT1)
78. Disolim – ag/s (PT1 and 2)
79. Dr. H2o limpiador de manos aséptico (PT 1)
80. Dr.h2o limpiador higienizante aseptico especial (PT 1,2 and 4)
81. Ds (PT 2 y 4)
82. Dybacol multi (PT 1,2 and 4)
83. Fletol (PT4)
84. Formula 2 who biodor (PT 1,2 and 4)
85. Formula 2 who biopulcher (PT 1,2 and 4)
86. Formulación 2 who (PT 1,2 and 4)
87. Futuregel hidroalcoholico desinfectante (PT 1)
88. G2 dosigel bact (PT 1,2 and 4)
89. Gel asepkol (PT1)
90. Gel de manos hidroalcohólico gelesán (pt1)
91. Gel desinfectante de manos aro (PT1)
92. Gel desinfectante de manos josmi (PT1)
93. Gel desinfectante de manos makro professional (PT1)
94. Gel desinfectante hidroalcoholico (PT1)
95. Gel desinfectante hidroalcoholico manos saray (PT1)
96. Gel hidroalcohólico (PT1)
97. Gel hidroalcohólico ceradi (PT 1,2 and 4)
98. Gel hidroalcoholico desinfectante Naturclean (PT 1,2 and 4)
99. Gel hidroalcoholico dimensa (PT1, 2 and 4)
100. Gel hidroalcohólico sanimusic toms (PT1, 2 and 4)
101. Germinet viru (PT1, 2, and 4)
102. Germinox pro (PT2 and 4)
103. Gh70 hidroalcohólico desinfectante para manos y superficies (PT 1,2 and 4)
104. Global c 210 (PT 1,2 and 4)
105. Gomagom sani+ desinfectante manos (PT1)
106. Gomagom sani+ desinfectante superficies (PT2 and 4)
107. Gomagom sani+ desinfectante textil (PT2)
108. Gomagom sani+ desinfectante universal (PT1, 2, and 4)
109. H 100% (PT2 and 4)
110. H.GEL (PT1)
111. H-0111b (PT1)
112. H-0141 - alcoflow des – limpiador desinfectante de superficies (PT2)

- 113.H-70 (PT2 and 4)
- 114.Hand clean adom (PT 1,2 and 4)
- 115.Hand disinfectant according to who recommendation (recipe 2) (PT1)
- 116.Hand hn 505 (PT1)
- 117.Hand hn 55 fresh (PT1)
- 118.Hand HN 56 Lotion (PT1, 2 and 4)
- 119.HC-alco handclean (PT1)
- 120.HC-alco surfclean (PT2 and 4)
- 121.Hidroalcohol biomca 1-propanol/agua 70% v/v (PT1)
- 122.Hidroalcohol biomca 2-propanol/agua 70% v/v (PT1)
- 123.Hidroalcohol gel (PT1)
- 124.Hidroalcoholico limplus (PT 1,2 and 4)
- 125.Hidroalcohólico tamar (PT 1,2 and 4)
- 126.Hidrobac (PT 1,2 and 4)
- 127.Hidrosan (PT 1,2 and 4)
- 128.Higisol 70 (PT 1,2 and 4)
- 129.Higisol 70 gel desinfectante de manos (PT1)
- 130.Hygiderm (PT 1)
- 131.Hygien 75 (PT 1,2 and 4)
- 132.Instant sani+ desinfectante manos (PT1)
- 133.Instant sani+ desinfectante superficies (PT2 and 4)
- 134.Instant sani+ desinfectante textil (PT2)
- 135.Instant sani+ desinfectante universal (PT1, 2, and 4)
- 136.Interdes (PT 1,2 and 4)
- 137.Isoprotec manos (PT1)
- 138.Isoprotec superficies (PT2 and 4)
- 139.Jemaquimp desinfectante de manos hidroalcoholico (PT 1,2 and 4)
- 140.K11n gel de manos (PT1)
- 141.Klash 962 (PT1)
- 142.Licogel t (PT 1,2 and 4)
- 143.Limger H (PT2 and 4)
- 144.Lm-1 top protect (PT 1,2 and 4)
- 145.Lm-4 top protect (PT 1,2 and 4)
- 146.Loción hidroalcohólica desinfectante de manos aro (PT1)
- 147.Loción hidroalcohólica desinfectante de manos josmi (PT1)
- 148.Loción hidroalcohólica desinfectante de manos makro professional (PT1)
- 149.Lsm gel (PT1, 2 and 4)
- 150.Manibac (PT 1,2 and 4)
- 151.Marcol – 400 (PT2)
- 152.Marhand hidroalcoholico (PT1, 2, and 4)
- 153.Math disinf-70 - solución desinfectante para pulverizar (PT 2 and 4)
- 154.Math-gel - gel desinfectante para manos (PT1)
- 155.Mikro mk 100 (PT 2 and 4)
- 156.Mikro mk 300 (PT 1,2 and 4)
- 157.Multiusos desinfectante jaguar (PT 1,2 and 4)

- 158.Oceano (PT1, 2 and 4)
- 159.Oceano Plus (PT1, 2 and 4)
- 160.Poly vir (PT1, 2 and 4)
- 161.Prodescare (PT1)
- 162.Prodesvir (PT 2 and 4)
- 163.Protectol schützt (i) (PT1)
- 164.Provir-Alc (PT1, 2 andv 4)
- 165.Pt-aktiv (PT1, 2, and 4)
- 166.Pulcro\_c19 (PT 1,2 and 4)
- 167.Qalcohol (PT1, 2 and 4)
- 168.Quilosa health - gel de manos desinfectante (PT1)
- 169.Quimasul a-2035 desinfectante antiséptico para piel sana (PT 1,2 and 4)
- 170.Quimasul a-2039 desinfectante de superficies (PT 1,2 and 4)
- 171.Relber alcohol gel (PT1)
- 172.Relber hidroalcohol liquido (PT 2 and 4)
- 173.Sagiter H biocida (PT1, 2 and 4)
- 174.Sanibac (PT 1,2 and 4)
- 175.Saniberk (PT 1,2 and 4)
- 176.Sani-Col (PT1, 2 and 4)
- 177.Sanihandol (PT 1,2 and 4)
- 178.Sanik-net desinfectante superficies (PT 1,2 and 4)
- 179.Sanimusic toms desinfeccion especifica (PT 2 and 4)
- 180.Saniplus textil (PT2)
- 181.Sanisport gel hidroalcoholico (PT 1,2 and 4)
- 182.Sanisport locion desinfectante (PT 1,2 and 4)
- 183.Sanit ipa ne (PT 1,2 and 4)
- 184.Sanitem-70 (PT 1 and 2)
- 185.Saniter (PT1, 2 and 4)
- 186.Saniter col (PT 1,2 and 4)
- 187.SaniWhater desinfectante manos (PT1)
- 188.SaniWhater desinfectante multiusos (PT1, 2, and 4)
- 189.SaniWhater desinfectante superficies (PT2 and 4)
- 190.SaniWhater desinfectante textil (PT2)
- 191.Sd-1 solucion hidroalcohólica (PT1)
- 192.Sd-2 gel hidroalcohólico (PT1)
- 193.Sd-3 desinfectante para superficies (PT2)
- 194.Sensi manos (PT 1,2 and 4)
- 195.Seqens solucion hidroalcohólica (PT1)
- 196.Ser-blue (PT1)
- 197.Ser-green (PT1)
- 198.Soap h50 (PT1, 2 and 4)
- 199.Solución antiséptica desinfectante de manos kinefis (PT1)
- 200.Solución antiséptica desinfectante de manos vitale (PT1)
- 201.Solución hidroalcohólica biomca 1-propanol/agua 70% v/v (PT1)
- 202.Solución hidroalcohólica biomca 2-propanol/agua 70% v/v (PT1)
- 203.Solución hidroalcoholica desinfectante (PT 1,2 and 4)

204.Solución hidroalcohólica desinfectante de manos (PT1)  
205.Solución hidroalcoholica limpieza de manos sin agua con glicerina (PT1)  
206.Spray hidroalcohólico desinfectante ama hogar(PT 1,2 and 4)  
207.Titanium health - gel de manos desinfectante (PT1)  
208.Toilman b.a.c. (PT 1,2 and 4)  
209.Upindesin (PT 1,2 and 4)  
210.Viraclean desinfectante hidroalcoholico de superficies y textiles (PT 1,2 and 4)  
211.Viricin-Pro (PT1, 2 and 4)  
212.Viricit multiusos (PT2 and 4)  
213.Viricitol multiusos (PT2 and 4)  
214.Viriclinic (PT2)  
215.Virisol multiusos (PT2 and 4)  
216.Viriram (PT 2 and 4)  
217.VirolOxy Desinfectante manos (PT1)  
218.VirolOxy Desinfectante multiusos (PT1, 2, and 4)  
219.VirolOxy Desinfectante superficies (PT2 and 4)  
220.VirolOxy Desinfectante textil (PT2)  
221.Virpro – cns (PT 1,2 and 4)  
222.Virubac 75 (PT1, 2 and 4)  
223.Virucida superficies ul (PT2)  
224.Virucida textil ul (PT2)  
225.Virugel plus antiséptico hidroalcoholico para piel sana y desinfectante de superficies (PT 1,2 and 4)

- Product type

PT 1, PT 2, PT4

- Active substance(s)

- Propan-1-ol  
- Propan-2-ol

- Target organism(s)

SARS-CoV-2

- User category

Non-professional user (general public)  
Professional user  
Trained professional

- Starting date of the action based on Art. 55 (1) of the BPR

24/09/2020

- End date of the action based on Art. 55 (1) of the BPR

24/03/2021

- Description of danger the derogation is intended to address

danger to public health

Due to a potential worsening of the pandemic situation caused by the coronavirus disease (SARS CoV 2), it is absolutely essential to ensure that the demand of disinfectant products is covered in order to contain the spread of the virus and protect the population.

In addition, the disinfectant's market is quite globalized and any increase of the demand on third countries that compete for the active substances or raw materials may produce a shortage of biocidal active substances and biocide products, which will endanger the public health in ES. Considering the latter, it is also necessary to authorize the products and suppliers of the active substances indicated above.

danger to animal health

(describe briefly the danger, the area affected and the effects of the danger)

danger to environment

(describe briefly the danger, the area affected and the effects of the danger)

- Geographical area of use

Spain

- Absence of any other means to contain the danger

Shortage due to SARS-CoV-2 outbreaks

- Limited and controlled use

The competent authority is already in possession of information on the source of the active substances and products which invoke this measure. In order to ensure that this exceptional situation does not constitute a loop in the ordinary procedures, the Ministry of Health is gathering information on the intentions of the holders of the exceptional authorization to follow the ordinary authorization path. This information will allow us to plan any future regulatory action.

- Applications submitted for the product and/or granted authorisations\*

The status of these products are under national laws in Spain.

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\* This section will be removed when publishing the notification in CIRCABC