



STATUTORY INSTRUMENTS.

**S.I. No. 396 of 2012**

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EUROPEAN COMMUNITIES (COSMETIC PRODUCTS)  
(AMENDMENT) REGULATIONS 2012

EUROPEAN COMMUNITIES (COSMETIC PRODUCTS)  
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I, JAMES REILLY, Minister for Health, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving further effect to Council Directive 76/768/EEC of 27 July 1976<sup>1</sup>, as amended by Council Directive 2011/84/EU of 20 September 2011<sup>2</sup>, hereby make the following regulations:

*Citation*

1. These Regulations may be cited as the European Communities (Cosmetic Products) (Amendment) Regulations 2012.

*Collective citation and construction*

2. The Principal Regulations and these Regulations may be cited together as the European Communities (Cosmetic Products) Regulations 2004 to 2012 and shall be construed together as one.

*Commencement*

3. These Regulations come into operation on 31 October 2012.

*Interpretation*

4. In these Regulations, “Principal Regulations” means the European Communities (Cosmetic Products) Regulations 2004 (S.I. No. 870 of 2004), as amended.

*Amendment of Regulation 4(1) of Principal Regulations*

5. Regulation 4(1) of the Principal Regulations is amended by substituting for the definition of “Directive” the following definition:

“ ‘Directive’ means Directive 76/768/EEC, as amended by Council Directive 79/661/EEC of 24 July 1979<sup>3</sup>, Commission Directive 82/147/EEC of 11 February 1982<sup>4</sup>, Council Directive 82/368/EEC of 17 May 1982<sup>5</sup>, Commission Directive 83/191/EEC of 30 March 1983<sup>6</sup>, Commission Directive 83/341/EEC of 29 June 1983<sup>7</sup>, Commission Directive 83/496/EEC of 22 September 1983<sup>8</sup>, Council Directive 83/574/EEC of 26 October 1983<sup>9</sup>, Commission Directive 84/415/EEC

<sup>1</sup>O.J No. L 262, 27.9.1976, p. 169.

<sup>2</sup>OJ No. L. 283, 29.10.2011, p. 36.

<sup>3</sup>OJ No. L 192, 31.7.1979, p. 35.

<sup>4</sup>OJ No. L 63, 6.3.1982, p. 26.

<sup>5</sup>OJ No. L 167, 15.6.1982, p. 1.

<sup>6</sup>OJ No. L 109, 26.4.1983, p. 25.

<sup>7</sup>OJ No. L 188, 13.7.1983, p. 15.

<sup>8</sup>OJ No. L 275, 8.10.1983, p. 20.

<sup>9</sup>OJ No. L 332, 28.11.1983, p. 38.

*Notice of the making of this Statutory Instrument was published in  
“Iris Oifigiúil” of 12th October, 2012.*

of 18 July 1984<sup>10</sup>, Commission Directive 85/391/EEC of 16 July 1985<sup>11</sup>, Commission Directive 86/179/EEC of 28 February 1986<sup>12</sup>, Commission Directive 86/199/EEC of 26 March 1986<sup>13</sup>, Commission Directive 87/137/EEC of 2 February 1987<sup>14</sup>, Commission Directive 88/233/EEC of 2 March 1988<sup>15</sup>, Council Directive 88/667/EEC of 21 December 1988<sup>16</sup>, Commission Directive 89/174/EEC of 21 February 1989<sup>17</sup>, Council Directive 89/679/EEC of 21 December 1989<sup>18</sup>, Commission Directive 90/121/EEC of 20 February 1990<sup>19</sup>, Commission Directive 91/184/EEC of 12 March 1991<sup>20</sup>, Commission Directive 92/8/EEC of 18 February 1992<sup>21</sup>, Commission Directive 92/86/EEC of 21 October 1992<sup>22</sup>, Council Directive 93/35/EEC of 14 June 1993<sup>23</sup>, Commission Directive 93/47/EEC of 22 June 1993<sup>24</sup>, Commission Directive 94/32/EC of 29 June 1994<sup>25</sup>, Commission Directive 95/34/EC of 10 July 1995<sup>26</sup>, Commission Directive 96/41/EC of 25 June 1996<sup>27</sup>, Commission Directive 97/1/EC of 10 January 1997<sup>28</sup>, Commission Directive 97/45/EC of 14 July 1997<sup>29</sup>, Commission Directive 98/16/EC of 5 March 1998<sup>30</sup>, Commission Directive 98/62/EC of 3 September 1998<sup>31</sup>, Commission Directive 2000/6/EC of 29 February 2000<sup>32</sup>, Commission Directive 2000/11/EC of 10 March 2000<sup>33</sup>, Commission Directive 2002/34/EC of 15 April 2002<sup>34</sup>, Commission Directive 2003/1/EC of 6 January 2003<sup>35</sup>, Commission Directive 2003/16/EC of 19 February 2003<sup>36</sup>, Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003<sup>37</sup>, Commission Directive 2003/80/EC of 5 September 2003<sup>38</sup>, Commission Directive 2003/83/EC of 24 September 2003<sup>39</sup>, Commission Directive 2004/87/EC

<sup>10</sup>OJ No. L 228, 25.8.1984, p. 31.

<sup>11</sup>OJ No. L 224, 22.8.1985, p. 40.

<sup>12</sup>OJ No. L 138, 24.5.1986, p. 40.

<sup>13</sup>OJ No. L 149, 3.6.1986, p. 38.

<sup>14</sup>OJ No. L 56, 26.2.1987, p. 20.

<sup>15</sup>OJ No. L 105, 26.4.1988, p. 11.

<sup>16</sup>OJ No. L 382, 31.12.1988, p. 46.

<sup>17</sup>OJ No. L 64, 8.3.1989, p. 10. As affected by Corrigendum to Commission Directive 89/174/EEC, OJ No. L 199, 13.7.1989, p. 23.

<sup>18</sup>OJ No. L 398, 30.12.1989, p. 25.

<sup>19</sup>OJ No. L 71, 17.3.1990, p. 40.

<sup>20</sup>OJ No. L 91, 12.4.1991, p. 59.

<sup>21</sup>OJ No. L 70, 17.3.1992, p. 23.

<sup>22</sup>OJ No. L 325, 11.11.1992, p. 18.

<sup>23</sup>OJ No. L 151, 23.6.1993, p. 32.

<sup>24</sup>OJ No. L 203, 13.8.1993, p. 24.

<sup>25</sup>OJ No. L 181, 15.7.1994, p. 31. As affected by Corrigendum to Commission Directive 94/32/EC, OJ No. L 273, 25.10.1994, p. 38.

<sup>26</sup>OJ No. L 167, 18.7.1995, p. 19.

<sup>27</sup>OJ No. L 198, 8.8.1996, p. 36.

<sup>28</sup>OJ No. L 16, 18.1.1997, p. 85.

<sup>29</sup>OJ No. L 196, 24.7.1997, p. 77.

<sup>30</sup>OJ No. L 77, 14.3.1998, p. 44.

<sup>31</sup>OJ No. L 253, 15.9.1998, p. 20.

<sup>32</sup>OJ No. L 56, 1.3.2000, p. 42.

<sup>33</sup>OJ No. L 65, 14.3.2000, p. 22.

<sup>34</sup>OJ No. L 102, 18.4.2002, p. 19. As affected by Corrigenda to Commission Directive 2002/34/EC, OJ No. L 341, 17.12.2002, p. 71 and OJ No. L 151, 19.6.2003, p. 44.

<sup>35</sup>OJ No. L 5, 10.1.2003, p. 14.

<sup>36</sup>OJ No. L 46, 20.2.2003, p. 24.

<sup>37</sup>OJ No. L 66, 11.3.2003, p. 26.

<sup>38</sup>OJ No. L 224, 6.9.2003, p. 27. As affected by Corrigendum to Commission Directive 2003/80/EC, OJ No. L 58, 26.2.2004, p. 28.

<sup>39</sup>OJ No. L 238, 25.9.2003, p. 23. As affected by Corrigendum to Commission Directive 2003/83/EC, OJ No. L 58, 26.2.2004, p. 28.

of 7 September 2004<sup>40</sup>, Commission Directive 2004/88/EC of 7 September 2004<sup>41</sup>, Commission Directive 2004/93/EC of 21 September 2004<sup>42</sup>, Commission Directive 2004/94/EC of 15 September 2004<sup>43</sup>, Commission Directive 2005/9/EC of 28 January 2005<sup>44</sup>, Commission Directive 2005/42/EC of 20 June 2005<sup>45</sup>, Commission Directive 2005/52/EC of 9 September 2005<sup>46</sup>, Commission Directive 2005/80/EC of 21 November 2005<sup>47</sup>, Commission Directive 2006/65/EC of 19 July 2006<sup>48</sup>, Commission Directive 2006/78/EC of 29 September 2006<sup>49</sup>, Commission Directive 2007/1/EC of 29 January 2007<sup>50</sup>, Commission Directive 2007/17/EC of 22 March 2007<sup>51</sup>, Commission Directive 2007/22/EC of 17 April 2007<sup>52</sup>, Commission Directive 2007/53/EC of 29 August 2007<sup>53</sup>, Commission Directive 2007/54/EC of 29 August 2007<sup>54</sup>, Commission Directive 2007/67/EC of 22 November 2007<sup>55</sup>, Commission Directive 2008/14/EC of 15 February 2008<sup>56</sup>, Commission Directive 2008/42/EC of 3 April 2008<sup>57</sup>, Commission Directive 2008/88/EC of 23 September 2008<sup>58</sup>, Directive 2008/112/EC of the European Parliament and of the Council of 16 December 2008<sup>59</sup>, Commission Directive 2008/123/EC of 18 December 2008<sup>60</sup>, Commission Directive 2009/6/EC of 4 February 2009<sup>61</sup>, Commission Directive 2009/36/EC of 16 April 2009<sup>62</sup>, Commission Directive 2009/129/EC of 9 October 2009<sup>63</sup>, Commission Directive 2009/130/EC of 12 October 2009<sup>64</sup>, Commission Directive 2009/134/EC of 28 October 2009<sup>65</sup>, Commission Directive 2009/159/EU of 16 December 2009<sup>66</sup>, Commission Directive 2009/164/EU of 22 December 2009<sup>67</sup>, Commission

<sup>40</sup>OJ No. L 287, 8.9.2004, p. 4.

<sup>41</sup>OJ No. L 287, 8.9.2004, p. 5.

<sup>42</sup>OJ No. L 300, 25.9.2004, p. 13. As affected by Corrigendum to Commission Directive 2004/93/EC, OJ No. L 97, 15.4.2005, p. 63.

<sup>43</sup>OJ No. L 294, 17.9.2004, p. 28.

<sup>44</sup>OJ No. L 27, 29.1.2005, p. 46.

<sup>45</sup>OJ No. L 158, 21.6.2005, p. 17.

<sup>46</sup>OJ No. L 234, 10.9.2005, p. 9.

<sup>47</sup>OJ No. L 303, 22.11.2005, p. 32.

<sup>48</sup>OJ No. L 198, 20.7.2006, p. 11.

<sup>49</sup>OJ No. L 271, 30.9.2006, p. 56.

<sup>50</sup>OJ No. L 25, 1.2.2007, p. 9.

<sup>51</sup>OJ No. L 82, 23.3.2007, p. 27.

<sup>52</sup>OJ No. L 101, 18.4.2007, p. 11.

<sup>53</sup>OJ No. L 226, 30.8.2007, p. 19. As affected by Corrigendum to Commission Directive 2007/53/EC, OJ No. L 22, 25.1.2008, p. 21.

<sup>54</sup>OJ No. L 226, 30.8.2007, p. 21. As affected by Corrigendum to Commission Directive 2007/54/EC, OJ No. L 258, 4.10.2007, p. 44.

<sup>55</sup>OJ No. L 305, 23.11.2007, p. 22.

<sup>56</sup>OJ No. L 42, 16.2.2008, p. 43.

<sup>57</sup>OJ No. L 93, 4.4.2008, p. 13. As affected by Corrigendum to Commission Directive 2008/42/EC, OJ No. L 136, 24.5.2008, p. 52.

<sup>58</sup>OJ No. L 256, 24.9.2008, p. 12. As affected by Corrigendum to Commission Directive 2008/88/EC, OJ No. L 263, 2.10.2008, p. 26.

<sup>59</sup>OJ No. L 345, 23.12.2008, p. 68.

<sup>60</sup>OJ No. L 340, 19.12.2008, p. 71.

<sup>61</sup>OJ No. L 36, 5.2.2009, p. 15.

<sup>62</sup>OJ No. L 98, 17.4.2009, p. 31. As affected by Corrigendum to Commission Directive 2009/36/EC, OJ No. L 103, 23.4.2009, p. 30.

<sup>63</sup>OJ No. L 267, 10.10.2009, p. 18.

<sup>64</sup>OJ No. L 268, 13.10.2009, p. 5.

<sup>65</sup>OJ No. L 282, 29.10.2009, p. 15.

<sup>66</sup>OJ No. L 336, 18.12.2009, p. 29.

<sup>67</sup>OJ No. L 344, 23.12.2009, p. 41. As affected by Corrigendum to Commission Directive 2009/164/EU, OJ No. L 3, 7.1.2010, p. 30.

Directive 2010/3/EU of 1 February 2010<sup>68</sup>, Commission Directive 2010/4/EU of 8 February 2010<sup>69</sup>, Commission Directive 2011/59/EU of 13 May 2011<sup>70</sup> and Council Directive 2011/84/EU of 20 September 2011<sup>2</sup>”

*Amendments to the Schedule in Principal Regulations*

6. Part 1 of Schedule 3 to the Principal Regulations is amended by the substitution for Reference Number 12 of the following schedule:—

<sup>68</sup>OJ No. L 29, 2.2.2010, p. 5.

<sup>69</sup>OJ No. L 36, 9.2.2010, p. 21.

<sup>70</sup>OJ No. L 125, 14.5.2011, p.17

## SCHEDULE

Reference number	Substance	Restrictions			Conditions of use and warnings which must be printed on the label
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	b	c	d	e	f
'12	Hydrogen peroxide and other compounds or mixtures that release hydrogen peroxide, including carbamide peroxide and zinc peroxide	<p>(a) Hair care mixtures</p> <p>(b) Skin care mixtures</p> <p>(c) Nail hardening mixtures</p> <p>(d) Oral products, including mouth rinse, tooth paste and tooth whitening or bleaching products</p> <p>(e) Tooth whitening or bleaching products</p>	<p>(a) 12% of H<sub>2</sub>O<sub>2</sub> (40 volumes), present or released</p> <p>(b) 4% of H<sub>2</sub>O<sub>2</sub>, present or released</p> <p>(c) 2% of H<sub>2</sub>O<sub>2</sub>, present or released</p> <p>(d) ≤ 0.1 % of H<sub>2</sub>O<sub>2</sub>, present or released</p> <p>(e) &gt; 0.1 % ≤ 6% of H<sub>2</sub>O<sub>2</sub>, present or released</p>	<p>(e) To be only sold to dental practitioners. For each cycle of use, first use by dental practitioners as defined under Directive 2005/36/EC (*) or under their direct supervision if an equivalent level of safety is ensured. Afterwards to be provided to the consumer to complete the cycle of use.</p> <p>Not to be used on a person under 18 years of age.</p>	<p>(a) Wear suitable gloves</p> <p>(a) (b) (c) (e)</p> <p>Contains hydrogen peroxide</p> <p>Avoid contact with eyes</p> <p>Rinse immediately if product comes into contact with them.</p> <p>(e) Concentration of H<sub>2</sub>O<sub>2</sub> present or released indicated in percentage.</p> <p>Not to be used on a person under 18 years of age.</p> <p>To be only sold to dental practitioners. For each cycle of use, the first use to be only done by dental practitioners or under their direct supervision if an equivalent level of safety is ensured. Afterwards to be provided to the consumer to complete the cycle of use.'</p>



GIVEN under my Official Seal,  
10 October 2012.

JAMES REILLY,  
Minister for Health.

## EXPLANATORY NOTE

*(This note is not part of the Instrument and does not purport to be a legal interpretation.)*

These Regulations amend the European Communities (Cosmetic Products) Regulations 2004. They update the law in relation to the manufacture, marketing and sale of cosmetic products by the implementation of Council Directive 2011/84/EU of 20 September 2011. These Regulations may be cited as the European Communities (Cosmetic Products) (Amendment) Regulations 2012.

BAILE ÁTHA CLIATH  
 ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR  
 Le ceannach díreach ón  
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