



STATUTORY INSTRUMENTS.

**S.I. No. 723 of 2011**

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EUROPEAN COMMUNITIES (COSMETIC PRODUCTS)  
(AMENDMENT) REGULATIONS 2011

**(Prn. A11/2426)**

EUROPEAN COMMUNITIES (COSMETIC PRODUCTS)  
(AMENDMENT) REGULATIONS 2011

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 effect to Commission Directive 2011/59/EU of 13 May 2011<sup>1</sup>, hereby make the following regulations:

*Citation*

1. These Regulations may be cited as the European Communities (Cosmetic Products) (Amendment) Regulations 2011.

*Commencement*

2. These Regulations come into operation on 3 January 2012.

*Interpretation*

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

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

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

“‘Directive’ means Council Directive 76/768/EEC of 27 July 1976<sup>2</sup>, 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 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>,

<sup>1</sup>OJ No. L 125, 14.5.2011, p.17.

<sup>2</sup>OJ No. L 262, 27.9.1976, p. 169.

<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.

<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.

*Notice of the making of this Statutory Instrument was published in  
“Iris Oifigiúil” of 3rd January, 2012.*

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 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

<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

<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.

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 Directive 2010/3/EU of 1 February 2010<sup>68</sup>, Commission Directive 2010/4/EU of 8 February 2010<sup>69</sup> and Commission Directive 2011/59/EU of 13 May 2011<sup>1</sup>.”

<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.

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

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

*Amendments to Schedules to Principal Regulations*

5. The Schedules to the Principal Regulations are amended as provided for in the Schedule.

## SCHEDULE

1. Schedule 2 to the Principal Regulations is amended by the insertion of the following entry:

Reference No.	Chemical name/INCI-name	CAS Number EC Number
'1372	2-Aminophenol (o-Aminophenol; CI 76520) and its salts	CAS No 95-55-6/67845-79-8/51-19-4 EC No 202-431-1/267-335-4'

2. Part 1 of Schedule 3 to the Principal Regulations is amended as follows—

(a) the following entries are added:

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
'215	4-amino-3-nitrophenol (CAS No 610-81-1) (EC No 210-236-8)	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products	(b) 1.0 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.5 %	(a) As mentioned in reference number 205, column f (a)  (b) As mentioned in reference number 208, column f
216	2,7-Naphthalenediol (CAS No 582-17-2) (EC No 209-478-7)	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products	(b) 1.0 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.0 %	(a) As mentioned in reference number 205, column f (a)

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
217	m-Aminophenol (CAS No 591-27-5) (EC No 209-711-2) and its salts m-Aminophenol HCl (CAS No 51-81-0) (EC No 200-125-2) m-Aminophenol sulphate (CAS No 68239-81-6) (EC No 269-475-1) sodium m-Amino-phenol (CAS No 38171-54-9)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.2 %	As mentioned in reference number 205, column f (a)
218	2,6-Dihydroxy-3,4-dimethylpyridine (CAS No 84540-47-6) (EC No 283-141-2)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.0 %	As mentioned in reference number 205, column f (a)
222	2-Hydroxyethyl picramic acid (CAS No 99610-72-7) (EC No 412-520-9)	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products	(b) 2.0 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.5 %  For (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	(a) As mentioned in reference number 205, column f (a)

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
223	Methylaminophenol (CAS No 150-75-4) (EC No 205-768-2) and its sulphate p-Methylaminophenol sulphate (CAS No 55-55-0/ 1936-57-8) (EC No 200-237-1/ 217-706-1)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.68 % (as sulphate) — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	As mentioned in reference number 205, column f (a)
225	Ethanol, 2-[4-[Ethyl[(2-Hydroxyethyl) Amino]-2-Nitrophenyl]-Amino]-, (CAS No 104516-93-0) and its hydrochloride HC Blue No 12 (CAS No 132885- 85-9) (EC No 407-020-2)	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products	(b) 1.5 % (as hydrochloride)	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.75 % (as hydrochloride)  For (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	(a) As mentioned in reference number 205, column f (a)



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
227	3-Amino-2,4-dichlorophenol (CAS No 61693-42-3) (EC No 262-909-0) and its hydrochloride 3-Amino-2,4-dichlorophenol HCl (CAS No 61693-43-4)	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products	(b) 1.5 % (as hydrochloride)	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.5 % (as hydrochloride)	(a) As mentioned in reference number 205, column f (a)
230	Phenyl methyl pyrazolone (CAS No 89-25-8) (EC No 201-891-0)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.25 %	As mentioned in reference number 205, column f (a)
232	2-Methyl-5-hydroxyethylaminophenol (CAS No 55302-96-0) (EC No 259-583-7)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.5 % — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	As mentioned in reference number 205, column f (a)

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
234	Hydroxybenzomorpholine (CAS No 26021-57-8) (EC No 247-415-5)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.0 % — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	As mentioned in reference number 205, column f (a)
237	2,2'-(4-Amino-3-nitrophenyl) imino] bisethanol (CAS No 29705-39-3) and its hydrochloride HC Red No 13 (CAS No 94158-13-1) (EC No 303-083-4)	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products	(b) 2.5 % (as hydrochloride)	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.25 % (as hydrochloride)	(a) As mentioned in reference number 205, column f (a)
238	2,6-Dimethoxy-3,5-pyridinediamine (CAS No 85679-78-3 (free base)) and its hydrochloride 2,6-Dimethoxy-3,5-pyridinediamine HCl (CAS No 56216-28-5) (EC No 260-062-1)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.25 % (as hydrochloride)	As mentioned in reference number 205, column f (a)

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
239	HC Violet No 1 (CAS No 82576-75-8) (EC No 417-600-7)	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products	(b) 0.28 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.25 %  For (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	(a) As mentioned in reference number 205, column f (a)  (b) As mentioned in reference number 208, column f
241	1,5-Naphthalenediol (CAS No 83-56-7) (EC No 201-487-4)	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products	(b) 1.0 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.0 %	(a) As mentioned in reference number 205, column f (a)
242	Hydroxypropyl bis(N-hydroxyethyl-p-phenylenediamine) (CAS No 128729-30-6) and its tetrahydrochloride Hydroxypropyl bis(N-hydroxyethyl-p-phenylenediamine) HCl (CAS No 128729-28-2) (EC No 416-320-2)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.4 % (as tetrahydrochloride)	As mentioned in reference number 205, column f (a)

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
243	4-Amino-2-hydroxytoluene (CAS No 2835-95-2) (EC No 220-618-6)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.5 %	As mentioned in reference number 205, column f (a)
244	2,4-Diaminophenoxyethanol (CAS No 70643-19-5), its hydrochloride and its sulphate 2,4-Diaminophenoxyethanol HCl (CAS No 66422-95-5) (EC No 266-357-1) 2,4-Diaminophenoxyethanol sulphate (CAS No 70643-20-8) (EC No 274-713-2)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2.0 % (as hydrochloride)	As mentioned in reference number 205, column f (a)
245	2-Methylresorcinol (CAS No 608-25-3) (EC No 210-155-8)	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products	(b) 1.8 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.8 %	(a) As mentioned in reference number 205, column f (a)
246	4-Amino-m-cresol (CAS No 2835-99-6) (EC No 220-621-2)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.5 %	As mentioned in reference number 205, column f (a)

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
248	2-Amino-4-hydroxyethylaminoanisole (CAS No 83763-47-7) (EC No 280-733-2) and its sulphate 2-Amino-4-hydroxyethylaminoanisole sulphate (CAS No 83763-48-8) (EC No 280-734-8)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.5 % (as sulphate) — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	As mentioned in reference number 205, column f (a)
249	Hydroxyethyl-3,4-methylenedioxyaniline and its hydrochloride Hydroxyethyl-3,4-methylenedioxyaniline HCl (CAS No 94158-14-2) (EC No 303-085-5)	Hair dye substance in oxidative hair dye products		After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.5 % — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	As mentioned in reference number 205, column f (a)
250	3-Nitro-p-hydroxyethylamino-phenol (CAS No 65235-31-6) (EC No 265-648-0)	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products	(b) 1.85 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 3.0 %  For (a) and (b): — Do not use with nitrosating systems — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	(a) As mentioned in reference number 205, column f (a)  (b) As mentioned in reference number 208, column f

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
251	4-Nitrophenyl aminoethylurea (CAS No 27080-42-8) (EC No 410-700-1)	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products	(b) 0.5 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0.25 %  For (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	(a) As mentioned in reference number 205, column f (a)
252	2-Amino-6-chloro- 4-nitrophenol (CAS No 6358-09- 4) (EC No 228- 762-1)	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products	(b) 2.0 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2.0 %	(a) As mentioned in reference number 205, column f (a)  (b) As mentioned in reference number 208, column f'

(b) the entry with reference number 201 is replaced by the following:

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	
'201	2-Chloro-6-ethylamino-4-nitrophenol (CAS No 131657-78-8) (EC No 411-440-1)	(a) Hair dye substance in oxidative hair dye products  (b) Hair dye substance in non-oxidative hair dye products	(b) 3.0 %	(a) After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 1.5 %  (a) and (b): — Do not use with nitrosating agents — Maximum nitrosamine content: 50 µg/kg — Keep in nitrite-free containers	(a) As mentioned in reference number 205, column f (a)

3. Part 2 of Schedule 3 to the Principal Regulations is amended as follows—

- (a) the entries with reference numbers 3 to 6, 11, 12, 16, 19 to 22, 25, 27, 31 to 39, 44, 48, 49, 55 and 56 are deleted;
- (b) in the entries with reference numbers 10 and 50, in column g, the date '31.12.2010' is replaced by '31.12.2011'.



GIVEN under my Official Seal,  
21 December 2011.

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 Commission Directive 2011/59/EU of 13 May 2011. These Regulations may be cited as the European Communities (Cosmetic Products) (Amendment) Regulations 2011.



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