BUREAU CIRCULAR
No. 12 series 1997

TO : ALL COSMETIC MANUFACTURERS, TRADERS, IMPORTERS AND PARTIES CONCERNED

SUBJECT : 1997 UPDATED LISTING OF COSMETIC INGREDIENTS

The BFAD Management Committee, in its meeting on August 28, 1997 has adopted and approved the updated technical standards and requirements set for cosmetic ingredients as recommended by the Joint BFAD and Cosmetic Industry Study Group’s Technical Committee. As such, the sections of Bureau Circular No. 19-A series of 1997 hereunder described are amended by the listings of cosmetic ingredients hereunto appended, to wit:

Section III - Restricted Ingredients For Use In Cosmetics

Table I : List Of Substances Which Cosmetics Products Must Not Contain Except Subject To The Restrictions And Conditions Specified

Table II : List Of Preservatives Which Cosmetic Products May Contain Subject To The Restrictions And Conditions Specified

Table III : List Of Preservatives Provisionally Allowed

Section IV - Non-Permissible Colors In Cosmetics

Table IV : Non-Permissible Colors In Cosmetics

Section V - Permissible Color Additives

Table V : Permissible Color Additives; List Of Colorants Restricted/Allowed For Cosmetic Products

Section VI: Sunscreen Agents

Table VI : List Of Provisionally Allowed Colors In Cosmetic Preparations

Table VII : List Of Sunscreen Agents Which Cosmetics Products May Contain

Table VIII : List Of Sunscreen Agents Which Cosmetics Products May Provisionally Contain

Table IX : List Of Substances Which Must Not Form Part Of The Composition Of Cosmetic Products
Additionally, BFAD has decided to extend the approval of products containing benzethonium chloride only up to December 31, 1997 in view of the ban of the said ingredient under the European Economic Community’s (EEC) August 1996 Directive, unless additional safety data on the same are found before December 31, 1997.

As provided for in Section IX of Bureau-Memorandum Circular 19-A s 1992, "the validity period of substances or ingredients provisionally allowed will automatically be considered extended until the same is either delisted/deleted as having been considered by BFAD as permissible or restricted substances in cosmetics."

This is for the information and guidance of all the parties concerned.

(Sgd) QUINTIN L. KINTANAR, M.D.,Ph.D., CESO I
Director
<table>
<thead>
<tr>
<th>REF NO.</th>
<th>SUBSTANCE</th>
<th>Field of applications and/or use</th>
<th>Maximum allowable concentration in the finished cosmetic product</th>
<th>Other limitations and requirements</th>
<th>Conditions of use and warning which must be printed on the label</th>
</tr>
</thead>
</table>
| 1       | Boric Acid/Sodium Borate (Borax) | a) Talcs/Facial Cleansers  
b) Products for oral hygiene  
c) Other products | a) 5%  
b) 0.5%  
c) 3% | a) Not to be used in products for children under three years of age | See section 1.4.G |
| 2       | Thioglycolic acid and its salts | a) Hair waving or straightening products:  
- general use  
- professional use  
b) Depilatories  
c) Other hair care products which are removed after application | -8% ready for use pH 7-9.5  
-11% ready for use pH 7-9.5  
pH 7-12.7  
<2% ready for use pH 7-9.5 | Percentages calculated as thioglycolic acid/  
a) Contains thioglycolate.  
- Follow the instructions  
- Keep out of reach of children  
- Avoid contact with eyes, rinse immediately with plenty of water and consult a physician  
- For professional use only.  
- Wear suitable gloves.  
b) and c)  
- Contains thioglycolate.  
- Follow the instructions  
- Keep out of reach of children  
- Wear suitable gloves.  
c) - Contains thioglycolate.  
- Follow the instructions  
- Keep out of reach of children  
- Wear suitable gloves.  
See 1.4.1. |
| 3       | Thioglycolic acid esters | Hair waving or straightening products  
- general use  
- professional use | - 8% ready for use pH 6-9.5  
- 11% ready for use pH 6-9.5  
Percentages calculated as thioglycolic acid | - Contains thioglycolate.  
- Follow the instructions  
- Keep out of reach of children  
- Warning shall be the same as Thioglycolic acid and its salts  
- For professional use only  
- Wear suitable gloves  
See 1.4.1 |
| 4       | a) Biosulfur fluid  
b) Sulfur | Liquid Shampoos | 0.5-2.0%  
>2.0% | | |
| 5       | Low molecular wt. Hydrocarbon i.e. propane | Aerosol propellant for cosmetic appearing in the foam or paste | 10% | Water content in the cosmetic is not less than 40% of the total mass & the propellant is not more than 10% of the total mass. | |
| 6       | Ammonia | Hair Bleach | 6% calculated as NH3 | Above 2%; contains Ammonia | |
| 7       | Oxalic acid its esters and alkaline salts | Hair care products | 5% | For professional use only. | |
| 8       | Chlorates of alkali metals | a) Toothpaste  
b) Other uses | a) 5%  
b) 3% | | |
| 9       | M and p-Phenylenediamines, their N-substituted derivatives and their salts; N-substituted | Oxidizing colouring agents for hair dyeing  
- general use  
- professional use | 10% calculated as free base | a) Can cause an allergic reaction. Sensitivity test advisable before use.  
Contains phenylenediamines. Do not use to dye eyelashes or eyebrows. | |
<table>
<thead>
<tr>
<th></th>
<th>Chemicals and their uses</th>
<th>10% calculated as free base</th>
<th>Notes</th>
</tr>
</thead>
</table>
| 10 | Methylphenylamines, their N-substituted derivatives and their salts | Oxidizing colouring agents for hair dyeing | a) general use  
     | a) general use | 10% calculated as free base | a) Can cause an allergic reaction. Sensitivity test advisable before use.  
     | b) professional use | 10% calculated as free base | b) For professional use only. Contains phenylenediamines. Can cause an allergic reaction. Sensitivity test advisable before use. |
| 11 | 2,4-diaminophenol (Diaminophenols) | Oxidizing colouring agents for hair dyeing | a) general use  
     | a) general use | 10% calculated as free base | a) Can cause an allergic reaction. Sensitivity test advisable before use. Contains diaminophenols. Do not use to dye eyelashes or eyebrows.  
     | b) professional use | 10% calculated as free base | b) For professional use only. Contains diaminophenols. Can cause an allergic reaction. Sensitivity test advisable before use. |
| 12 | Hydrogen Peroxide & other components or mixtures that release hydrogen peroxide including carbamide & zinc peroxide | a) Hair care products  
     | a) 12% H2O2 (40 vol.) | a) Contains hydrogen peroxide. Avoid contact with eyes. Rinse eyes immediately if product comes into contact with them.  
     | b) Skin-care preparations  
     | b) 4% of H2O2 | (a)(b)(c)  
     | c) Nail hardening preparations  
     | c) 2% H2O2 | Contains hydrogen peroxide. Avoid contact with eyes. Rinse eyes immediately if product comes into contact with them.  
     | d) Oral Hygiene Products  
     | d) 0.1% of H2O2 | (a) Wear suitable gloves |
| 13 | Formaldehyde (Formalin) | Nail Hardeners | 5% calculated as formaldehyde | Protect cuticles with grease or oil. |
| 14 | Hydroquinone (1) (p-Hydroxyphenol) | (a) Oxidizing colouring agent for hair-dyeing | 2% | (a)  
     | 1) general use | 2% by weight  
     | 2) professional use | 4.5% by weight (3)  
     | 1) 2% by weight (3) | 1. Do not use to dye eyelashes or eyebrows. Rinse the eyes immediately if product comes into contact with them.  
     | 2) 4.5% by weight (3) | 2. For professional use only. Contains Hydroquinone. Rinse the eyes immediately if product comes into contact with them.  
     | 3) up to pH 12.7 |  
     | 4) up to pH 11 | |
| 15 | Potassium or sodium hydroxide (Caustic potash or caustic soda) | (a) Nail Cuticle Solvent  
     | a) 5% by weight (3) | (a)  
     | 1) general use | 1) 2% by weight (3)  
     | 2) professional use | 2. For professional use only. Avoid contact with eyes. Can cause blindness. Keep out of reach of children.  
     | c) pH adjuster  
     | c) up to pH 12.7 | (b)  
     | d) other uses as pH adjuster  
     | 1) general use | 2. For professional use only. Avoid contact with eyes. Can cause blindness.  
     | 2) professional use | (c) Keep out of reach of children. Avoid contact with eyes.  
<pre><code> | 3) depilatories | |
</code></pre>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>Alpha-naphthol (1-naphthol)</td>
<td>Colouring agent for hair dyeing</td>
<td>0.5%</td>
</tr>
<tr>
<td>17</td>
<td>Phenol and its alkali salts (Carbolic acid)</td>
<td>Soaps and shampoos</td>
<td>1% calculated as phenol</td>
</tr>
<tr>
<td>18</td>
<td>Pyrogallol (1) (1,2,3-Benzenetriol)</td>
<td>Oxidizing colouring agent for hair dyeing</td>
<td>5%</td>
</tr>
<tr>
<td>19</td>
<td>Resorcinol (1) (1,3-Benzenediol)</td>
<td>(a) Oxidizing colouring agent for hair dyeing</td>
<td>(a) 5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. general use</td>
<td>1. Contains resorcinol. Rinse hair well after application. Do not use to dye eyelashes or eyebrows. Rinse eyes immediately if product comes into contact with them.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. professional use</td>
<td>2. For professional use only. Contains pyrogallol. Rinse eyes immediately if product comes in contact with them.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. Hair lotions and shampoos</td>
<td>(b) 0.5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(c) Skin care</td>
<td>(b)(c) Contains resorcinol.</td>
</tr>
<tr>
<td>20</td>
<td>(a) Alkali sulphides</td>
<td>Depilatories</td>
<td>(a) 2% calculated as sulphur pH up to 12.7</td>
</tr>
<tr>
<td></td>
<td>(b) Alkaline earth sulphides</td>
<td></td>
<td>(b) 6% calculated as sulphur pH up to 12.7</td>
</tr>
<tr>
<td>21</td>
<td>Water-soluble zinc salts with the exception of zinc 4-hydroxybenzene sulphonate and zinc pyrithione</td>
<td></td>
<td>1% calculated as zinc</td>
</tr>
<tr>
<td>22</td>
<td>Zinc 4-hydroxybenzene sulphonate (Zinc paraphenol sulphate)</td>
<td>Deodorants, antiperspirants and astringent lotions</td>
<td>6% calculated as % of anhydrous substance</td>
</tr>
<tr>
<td>23</td>
<td>Ammonium monofluorophosphate</td>
<td>Oral hygiene products</td>
<td>0.15% calculated as F. When mixed with other fluoride compounds allowed total F concentration must not exceed 0.15%</td>
</tr>
<tr>
<td>24</td>
<td>Sodium monofluorophosphate</td>
<td>Ditto</td>
<td>0.15% Ditto</td>
</tr>
<tr>
<td>25</td>
<td>Potassium monofluorophosphate</td>
<td>Ditto</td>
<td>0.15% Ditto</td>
</tr>
<tr>
<td>26</td>
<td>Calcium monofluorophosphate</td>
<td>Ditto</td>
<td>0.15% Ditto</td>
</tr>
<tr>
<td>27</td>
<td>Calcium fluoride</td>
<td>Ditto</td>
<td>0.15% Ditto</td>
</tr>
<tr>
<td>28</td>
<td>Sodium fluoride</td>
<td>Ditto</td>
<td>0.15% Ditto</td>
</tr>
<tr>
<td>29</td>
<td>Potassium fluoride</td>
<td>Ditto</td>
<td>0.15% Ditto</td>
</tr>
<tr>
<td>30</td>
<td>Ammonium fluoride</td>
<td>Ditto</td>
<td>0.15% Ditto</td>
</tr>
<tr>
<td>31</td>
<td>Aluminum</td>
<td>Ditto</td>
<td>0.15% Ditto</td>
</tr>
</tbody>
</table>

Contains: alpha-naphthol, phenol, pyrogallol, resorcinol.
<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>32</td>
<td>Stannous fluoride</td>
<td>Ditto</td>
<td>0.15% Ditto</td>
</tr>
<tr>
<td></td>
<td>Contains Stannous fluoride</td>
<td></td>
<td></td>
</tr>
<tr>
<td>33</td>
<td>Hexadecyl ammonium fluoride</td>
<td>Ditto</td>
<td>0.15% Ditto</td>
</tr>
<tr>
<td></td>
<td>Contains Hexadecyl ammonium fluoride</td>
<td></td>
<td></td>
</tr>
<tr>
<td>34</td>
<td>3-(N-Hexadecyl-N-2-hydroxyethylammonio) propylbis (2-hydroxyethyl) ammonium dihydrofluoride</td>
<td>Ditto</td>
<td>0.15% Ditto</td>
</tr>
<tr>
<td></td>
<td>Contains 3-(N-Hexadecyl-N-2-hydroxyethylammonio) propylbis (2-hydroxyethyl) ammonium dihydrofluoride</td>
<td></td>
<td></td>
</tr>
<tr>
<td>35</td>
<td>NN’N’-Tris (polyoxyethylene-N-hexa decyl-propylenediamine dihydro-fluoride</td>
<td>Ditto</td>
<td>0.15% Ditto</td>
</tr>
<tr>
<td></td>
<td>Contains NN’N’-Tris (polyoxyethylene-N-hexa decyl-propylenediamine dihydro-fluoride</td>
<td></td>
<td></td>
</tr>
<tr>
<td>36</td>
<td>Octadecenyl-ammonium fluoride</td>
<td>Ditto</td>
<td>0.15% Ditto</td>
</tr>
<tr>
<td></td>
<td>Contains Octadecenyl-ammonium fluoride</td>
<td></td>
<td></td>
</tr>
<tr>
<td>37</td>
<td>Sodium fluoro-silicate</td>
<td>Ditto</td>
<td>0.15% Ditto</td>
</tr>
<tr>
<td></td>
<td>Contains Sodium fluoro-silicate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>38</td>
<td>Potassium fluoro-silicate</td>
<td>Ditto</td>
<td>0.15% Ditto</td>
</tr>
<tr>
<td></td>
<td>Contains Potassium fluoro-silicate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>39</td>
<td>Ammonium fluoro-silicate</td>
<td>Ditto</td>
<td>0.15% Ditto</td>
</tr>
<tr>
<td></td>
<td>Contains Ammonium fluoro-silicate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>40</td>
<td>Magnesium fluoro-silicate</td>
<td>Ditto</td>
<td>0.15% Ditto</td>
</tr>
<tr>
<td></td>
<td>Contains Magnesium fluoro-silicate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>41</td>
<td>1,3-Bis (hydroxymethyl) imidazolidine-2-thione</td>
<td>a) Hair care preparations.</td>
<td>up to 2%</td>
</tr>
<tr>
<td></td>
<td>b) Nail care preparations.</td>
<td>up to 2%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Contains 1,3-Bis (hydroxymethyl) imidazolidine-2-thione</td>
<td></td>
<td></td>
</tr>
<tr>
<td>42</td>
<td>Benzyl alcohol</td>
<td>Solvents, perfumes and flavourings</td>
<td>0.15% calculated as F.</td>
</tr>
<tr>
<td></td>
<td>contains silver nitrate</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- rinse the eyes immediately if product comes into contact with them.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Contains selenium disulphide.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Avoid contact with eyes or damaged skin.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>43</td>
<td>Nicomethanol hydro-fluoride</td>
<td>Oral hygiene products</td>
<td>0.15% calculated as F.</td>
</tr>
<tr>
<td></td>
<td>When mixed with other fluorine compounds allowed total F concentration must not exceed 0.15%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>44</td>
<td>Silver nitrate</td>
<td>Solely for products intended for colouring eyelashes and eyebrows</td>
<td>4%</td>
</tr>
<tr>
<td></td>
<td>- Contains silver nitrate</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- rinse the eyes immediately if product comes into contact with them.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>45</td>
<td>Selenium disulphide</td>
<td>Anti-dandruff shampoos</td>
<td>1%</td>
</tr>
<tr>
<td></td>
<td>- Contains selenium disulphide.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Avoid contact with eyes or damaged skin.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>46</td>
<td>Aluminium chloride (aluminum chloride hexahydrate)</td>
<td>Anti-perspirant</td>
<td>15% or less calculated as the hexahydrate form in aqueous solution</td>
</tr>
<tr>
<td></td>
<td>Some users of the product will experience skin irritation. Apply to skin of underarm. Not to be used generally over the body.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>47</td>
<td>Aluminium chlorhydrate (chlorhydrol)</td>
<td>Ditto</td>
<td>25%</td>
</tr>
<tr>
<td></td>
<td>Do not apply to broken skin. If rash develops, discontinue use. Apply to skin of underarm. Not to be used generally over the body.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>48</td>
<td>Triclosan (Irgasan DP-300)</td>
<td>Deodorant Toothpaste</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>Irgasan DP300 is not to be formulated in feminine hygiene products</td>
<td></td>
<td></td>
</tr>
<tr>
<td>49</td>
<td>Zinc phenolcarbonate</td>
<td>Deodorate</td>
<td>2%</td>
</tr>
<tr>
<td>50</td>
<td>Quaternary ammonium compounds</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compound</td>
<td>Formulation</td>
<td>Concentration</td>
<td>Notes</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>--------------------------------------</td>
<td>---------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>Cetylpyridinium chloride</td>
<td>Feminine wash</td>
<td>0.1%</td>
<td>For external use only. Avoid contact with eyes if contact with eyes, rinse thoroughly with water. If irritation persists consult a physician.</td>
</tr>
<tr>
<td>Benzethonium chloride</td>
<td>Feminine wash</td>
<td>0.1%</td>
<td></td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>Feminine wash</td>
<td>0.5%</td>
<td></td>
</tr>
<tr>
<td>Alkyl (C12-C22) trimethyl ammonium chloride</td>
<td>Feminine wash</td>
<td>0.1%</td>
<td></td>
</tr>
<tr>
<td>1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3-dimethylbuten-2-one (Climbazole)</td>
<td>Hair Shampoo</td>
<td>0.1%</td>
<td></td>
</tr>
<tr>
<td>Trichlorocarbanilide (TCC)</td>
<td>Deodorant</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td>Pyrithione Zinc (Zinc Pyrithione) (Zinc Omadine)</td>
<td>a) hairgroom preparation</td>
<td>a) 0.25%</td>
<td>a) Leave-on products only.</td>
</tr>
<tr>
<td></td>
<td>b) hair shampoo</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aluminum zirconium chloride hydroxide complexes</td>
<td>Anti-perspirants</td>
<td>20% as anhydrous aluminum zirconium chloride hydroxide</td>
<td>1) the ratio of the number of aluminum atoms to that of zirconium atoms must be between 20 and 10.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.4% as zirconium</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2) The ratio of the number of (Al+Zr) atoms to that of chlorine atoms must be between 0.9 and 2.1.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3) Prohibited in aerosol dispensers (sprays)</td>
</tr>
<tr>
<td>Quinolin-8-ol and bis (8-hydroxyquinolinium) sulphate</td>
<td>a) stabilizer for hydrogen peroxide</td>
<td>a)0.3% calculated as base</td>
<td>Do not apply to damages or broken skin.</td>
</tr>
<tr>
<td></td>
<td>b) hair-care preparations</td>
<td>0.03% calculated as base</td>
<td></td>
</tr>
<tr>
<td>1-hydroxy-ethylidene-diphosphonic acid &amp; its salts (etidronic acid &amp; its salts)</td>
<td>Hair-care</td>
<td>1.5% expressed as etidronic acid</td>
<td>Keep away from children - avoid contact with eyes - wash hands after use contains lead acetate. Do not use to dye eyelashes, eyebrows, moustache. - if irritation develops, discontinue use</td>
</tr>
<tr>
<td>Lead acetate</td>
<td>Only for hair dyeing</td>
<td>0.6% cakcykated as kead</td>
<td></td>
</tr>
<tr>
<td>Magnesium fluoride</td>
<td>Oral hygiene products</td>
<td>0.15% calculated as F. When mixed with other allowed fluoride compounds total F concentration must not exceed 0.15%</td>
<td>Contains magnesium fluoride</td>
</tr>
<tr>
<td>Piroctone Olamine (Octopirox)</td>
<td>Antidandruff Shampoo/conditioners</td>
<td>1.0%</td>
<td>-for external only - avoid contact with eyes - if irritation persists, contact</td>
</tr>
<tr>
<td>60</td>
<td>a physician 60-methylcoumarin</td>
<td>Oral hygiene products</td>
<td>0.003%</td>
</tr>
</tbody>
</table>
| 61 | Strontium Chloride hexahydrate | Toothpaste | 3.5% calculated as strontium. When mixed with other permitted strontium products the total strontium content must not exceed 3.4% | -contains strontium chloride  
-frequent use by children is not advisable |
| 62 | Strontium acetate hexahydrate | Toothpaste | 3.5% calculated as strontium. When mixed with other permitted strontium products the total strontium content must not exceed 3.4% | -contains strontium chloride  
-frequent use by children is not advisable |
| 63 | Hydrated Magnesium Silicate (Talc) | a) powdery products intended to be used for children under 3 years of age  
b) other products |  | Powder products: Keep powder away from baby’s nose and mouth. |
| 64 | Trialkanolamines a) non-rinse off products  
b) other products | a) 2.5% |  | a)  
-Do not use with nitrosating systems  
-Minimum purity: 99%  
-Maximum secondary alkanolamine content: 0.5%  
(concerns raw materials)  
-Maximum N-nitrosodi-alkanolamine content, 500g/kg  
-Keep in Nitrate-Free containers |
| 65 | Fatty Acid dialkanolamides | Maximum dialkanolamine content 0.5% |  | -Do not use with nitrosating systems  
-Minimum purity: 99%  
-Maximum dialkanolamine content: 5%  
(concerns raw materials)  
-Maximum N-nitrosodi-alkanolamine content, 500g/kg  
-Keep in Nitrate-Free containers |
| 66 | Monoalkanolamines | Maximum dialkanolamine content: 0.5% |  | -Do not use with nitrosating systems  
-Minimum purity: 99%  
-Maximum secondary alkanolamine content: 0.5%  
(concerns raw materials)  
-Maximum N-nitrosodi-alkanolamine content, 500g/kg  
-Keep in Nitrate-Free containers |
| 67 | Salicylic Acid | Skin Care | <2.0% | 1. Not to be used by children under 3 yrs. of age.  
2. Not to be used in large portion of the body.  
3. Not to be used for |
<table>
<thead>
<tr>
<th></th>
<th>Substance</th>
<th>Description</th>
<th>Concentration</th>
<th>Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>68</td>
<td>Strontium Hydroxide</td>
<td>PH regulator in depilatory products</td>
<td>3.5% calculated as Strontium Max. pH of 12.7</td>
<td>- keep out of reach of children.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- avoid contact with eyes</td>
</tr>
<tr>
<td>69</td>
<td>Strontium Peroxide</td>
<td>- Rinse off hair care preparations - professional use</td>
<td>4.5% calculated as strontium in ready for use preparation</td>
<td>- avoid contact with eyes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- rinse eyes immediately if product comes in contact with them</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- for professional use only</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- wear suitable gloves</td>
</tr>
</tbody>
</table>

1) These substances may be used singly or in combination provided that the sum of the ratios of the levels of each of them in the cosmetic product expressed with reference to the maximum level authorized does not exceed 1. Only if the concentration exceeds 0.05%.
## TABLE II - LIST OF PRESERVATIVES WHICH COSMETIC PRODUCTS MAY CONTAIN SUBJECT TO THE RESTRICTIONS AND CONDITIONS LAID DOWN

<table>
<thead>
<tr>
<th>Ref. No.</th>
<th>Substance</th>
<th>Maximum allowable concentration</th>
<th>Limitation and requirements</th>
<th>Conditions of use and warning which must be printed on the label</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Benzenecarboxylic acid, its salts and esters (Benzoic acid, its salts and esters)</td>
<td>0.5% (acid)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Propionic acid and its salt</td>
<td>2% (acid)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>2-Hydroxybenzoic acid and its salts (Salicylic acid and its salts)</td>
<td>0.5% (acid)</td>
<td>Not to be used in preparations for children under 3 years of age, except for shampoos</td>
<td>Not to be used for children under 3 years of age (1)</td>
</tr>
<tr>
<td>4</td>
<td>Hexa-2, 4-dianoic acid and its salts (Sorbic acid and its salts)</td>
<td>0.6% (acid)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Formaldehyde and paraformaldehyde</td>
<td>0.2% (except for products for oral hygiene)</td>
<td>Prohibited in aerosol dispensers (sprays)</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Biphenyl-2-ol and its salts (o-phenyl phenol)</td>
<td>0.2% expressed as the phenol</td>
<td>Authorized in rinsed off products. Forbidden in products for oral hygiene.</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Zinc Pyrithione (Zinc Omadine)</td>
<td>0.5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Inorganic sulphites and hydrogensulphites</td>
<td>0.2% expressed as free SO2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Sodium iodate</td>
<td>0.1%</td>
<td>Rinse-off products only</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Chlorobutanol (INN)</td>
<td>0.5%</td>
<td>Prohibited in aerosol dispensers (sprays)</td>
<td>Contains chlorobutanol</td>
</tr>
<tr>
<td>11</td>
<td>4-hydroxybenzoic acid and its salts (p-hydroxybenzoic acid)</td>
<td>0.4% (acid) for ester, 0.8% (acid) for mixtures of esters</td>
<td>Prohibited in aerosol dispensers (sprays)</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>3-Acetyl-6-methylpyran-2,4(3H)-dione and its salts (Dehydroacetic acid)</td>
<td>0.6% (acid)</td>
<td>Prohibited in aerosol dispensers (sprays)</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Formic acid</td>
<td>0.5% (acid)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>3,3-Dibromo-4,4-hexamethylene-dioxydibenzamidine (Dibromohexamidine) and its salts (including isethionate)</td>
<td>0.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Under-10-enoic acid and salts (Undecylenic acid)</td>
<td>0.2%(acid)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>Hexetidine (INN)</td>
<td>0.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>5-Bromo-5-nitro-1,3 dioxane (Bronidox L)</td>
<td>0.1%</td>
<td>Rinse-off products only. Avoid formation of nitrosamines</td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>2-Bromo-2-nitro-1, 3-propanediol (Bronopol)</td>
<td>0.1%</td>
<td>Avoid formation of nitrosamines</td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>2, 4-Dichlorobenzyl alcohol</td>
<td>0.15%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>3,4,4-Trichlorocarbanilide (Triclocarban)</td>
<td>0.2%</td>
<td>Purity criteria: 3,3',4,4'-Tetra-chloro-azobenzene less than</td>
<td></td>
</tr>
<tr>
<td>No.</td>
<td>Ingredient</td>
<td>Concentration</td>
<td>Notes</td>
<td></td>
</tr>
<tr>
<td>-----</td>
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<td>---------------</td>
<td>-------</td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>4-chloro-m-cresol (Chlorocresol)</td>
<td>0.2%</td>
<td>Prohibited in products intended to come into contact with mucus membranes</td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>Triclosan (INN) (Irgasan DP-300)</td>
<td>0.3%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>23</td>
<td>4-Chloro-3,5-xylenol Triclosan (INN) (Irgasan DP-300)</td>
<td>0.5% 0.35</td>
<td></td>
<td></td>
</tr>
<tr>
<td>24</td>
<td>3,3'-Bis (1-hydroxymethyl-2,5-dioxoimidazolidin-4-yl)-1,1'-methyleneurea (&quot;Imidazolidinyl urea&quot;)</td>
<td>0.6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>25</td>
<td>Poly(1-hexamethylenebiquanide hydrochloride</td>
<td>0.3%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>26</td>
<td>2-Phenoxyethanol</td>
<td>1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>27</td>
<td>Hexamethylenetetramine (methenamine) (INN) (Quaternium 15)</td>
<td>0.15%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>28</td>
<td>Methenamine 3chloroallylchloride (INNM)</td>
<td>0.2%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>29</td>
<td>1-(4-Chlorophenoxy)-1-(imidazol-1-yl) 3,3-diaminobutan-2-one (Climbazole)</td>
<td>0.5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30</td>
<td>1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione</td>
<td>0.6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>31</td>
<td>Benzyl alcohol</td>
<td>1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>32</td>
<td>1-hydroxy-4-methyl-6(2,4,4-trimethylpentyl) 2-pyridon and its monoethanolamine salt (Piroctone Olamine), Octopirox</td>
<td>1% 0.5%</td>
<td>For rinsed off products For other products</td>
<td></td>
</tr>
<tr>
<td>33</td>
<td>6,6-Dibromo-4, 4-dichloro-2,3'-methylene-diphenol (Bromochlorophen)</td>
<td>0.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>34</td>
<td>4-Isopropyl-m-cresol</td>
<td>0.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>35</td>
<td>Mixture of 5-Chloro-2-methyl-isothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one with magnesium chloride and magnesium nitrate (Kathon CG)</td>
<td>0.0015% (of a mixture in the ratio 3:1 of 5-chloro-2-methylisothiazol-3 (2H) one &amp; 2-methylisothiazol-3 (2H) one) Kathon CG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>36</td>
<td>2-benzyl-4-chlorophenol (Chlorophene)</td>
<td>0.2%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>37</td>
<td>2-Chloroacetamide</td>
<td>0.3%</td>
<td>Contains chloroacetamide</td>
<td></td>
</tr>
<tr>
<td>38</td>
<td>Chlorhexidine (INN) and its digluconate, diacetate and dihydrochloride</td>
<td>0.3% expressed as chlorhexidine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>39</td>
<td>1-Phenoxypropan-2-ol</td>
<td>1.0%</td>
<td>Only for rinse-off products</td>
<td></td>
</tr>
<tr>
<td>40</td>
<td>Alkyl (C12-C22) trimethyl ammonium, bromide and chloride</td>
<td>0.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>41</td>
<td>4,4-dimethyl-1,3-oxazolidine</td>
<td>0.1%</td>
<td>The pH of the finished product must not be lower</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>42</td>
<td>N-(Hydroxymethyl)-N-(dihydroxymethyl-1,3-dioxo-2,5-imidazolidinyl-4)-N'-hydromethyl) urea (Idiazolidinyl Urea)</td>
<td>0.5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>43</td>
<td>Butylated hydroxyanisole</td>
<td>0.2%</td>
<td>For products rinsed off after use</td>
<td></td>
</tr>
<tr>
<td>44</td>
<td>Hexamidine (INN) &amp; its salts including Isethionate &amp; 4-hydroxy benzoate</td>
<td>0.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>45</td>
<td>N-(Trichloromethylthio)-cyclohex-4-ene-1,2-dicarboximide (Captan ISO)</td>
<td>0.5%</td>
<td>Do not use with lime or other strong alkali</td>
<td></td>
</tr>
<tr>
<td>46</td>
<td>Chloro-N-(hydroxymethyl)acetamide</td>
<td>0.3% for the chloro-acetamide</td>
<td>For products rinsed off after use</td>
<td></td>
</tr>
<tr>
<td>47</td>
<td>Phenonip</td>
<td>1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>48</td>
<td>Cetyl pyridinium chloride</td>
<td>0.01-0.05%</td>
<td>For products that come in contact with the mucous membrane</td>
<td>0.01-1%</td>
</tr>
</tbody>
</table>

(1) Sole for products which might be used for children under 3 years of age and which remain in prolonged contact with skin.
### TABLE III - LIST OF PRESERVATIVES PROVISIONALLY ALLOWED

<table>
<thead>
<tr>
<th>REF. NO.</th>
<th>SUBSTANCE</th>
<th>MAXIMUM ALLOWABLE CONCENTRATION</th>
<th>LIMITATIONS AND REQUIREMENTS</th>
<th>CONDITIONS OF USE AND WARNING WHICH MUST BE PRINTED ON THE LABEL</th>
<th>ALLOWED UNTIL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Chlorphenesin (INN)</td>
<td>0.30%</td>
<td></td>
<td></td>
<td>12-31-97</td>
</tr>
<tr>
<td>2</td>
<td>Benzethonium chloride (INN)</td>
<td>0.10%</td>
<td>Only for deodorant, hair care products and after shave products. Prohibited in the products intended to come into contact with mucous membrane</td>
<td></td>
<td>12-31-97</td>
</tr>
<tr>
<td>3</td>
<td>Benzalkonium chloride (INN), bromide and saccharinate</td>
<td>0.10%</td>
<td></td>
<td></td>
<td>12-31-97</td>
</tr>
<tr>
<td>4</td>
<td>Benzylhemiformal</td>
<td></td>
<td>For rinse-off products only</td>
<td></td>
<td>12-31-97</td>
</tr>
<tr>
<td>5</td>
<td>3-iodo-2-propynylbutyl carbamate</td>
<td></td>
<td></td>
<td></td>
<td>12-31-97</td>
</tr>
<tr>
<td>6</td>
<td>Sodium hydroxymethyl aminoacetate</td>
<td>0.10%</td>
<td></td>
<td></td>
<td>12-31-97</td>
</tr>
<tr>
<td>REF. NO</td>
<td>FD &amp; C Designation</td>
<td>Color Index Number</td>
<td>Common Name</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------</td>
<td>--------------------------</td>
<td>--------------------</td>
<td>---------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>FD &amp; C Green No. 1</td>
<td>CL 42085</td>
<td>Guinea Green B</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>FD &amp; C Green No. 2</td>
<td>CL 42095</td>
<td>Light Green SF Yellowish</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>FD &amp; C Red No. 1</td>
<td>CL 16155</td>
<td>Ponceau 3R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>FD &amp; C Violet No. 1</td>
<td></td>
<td>Wool Violet 4BN</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>D &amp; C Blue No. 7</td>
<td>CL 42052</td>
<td>Patent Blue NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>D &amp; C Red No. 5</td>
<td>CL 16150</td>
<td>Ponceau 2R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>D &amp; C Red No. 10</td>
<td>CL 15630</td>
<td>Lithol Red</td>
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</tr>
<tr>
<td>8</td>
<td>D &amp; C Red No. 11</td>
<td></td>
<td>Lithol Red CA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>D &amp; C Red No. 12</td>
<td></td>
<td>Lithol Red BA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>D &amp; C Red No. 13</td>
<td></td>
<td>Lithol Red SR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>D &amp; C Red No. 14</td>
<td>CL 15500</td>
<td>Lake Red D</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>D &amp; C Red No. 18</td>
<td>CL 26125</td>
<td>Oil Red OS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>D &amp; C Red No. 24</td>
<td>CL 45366</td>
<td>Tetrachlorofluorescein</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>D &amp; C Red No. 29</td>
<td>CL 45457</td>
<td>Bluish Orange TR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>D &amp; C Red No. 35</td>
<td>CL 12120</td>
<td>Toluidine Red</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>D &amp; C Red No. 37</td>
<td>CL 45170:3</td>
<td>Rhodamine B Stearate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>D &amp; C Red No. 38</td>
<td>CL 12350</td>
<td>Toluidine Maroon</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>D &amp; C Orange No. 8</td>
<td>CL 45365</td>
<td>Dichlorofluorescein</td>
<td></td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>D &amp; C Orange No. 14</td>
<td>CL 45456</td>
<td>Orange TR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>D &amp; C Orange No. 16</td>
<td>CL 45371</td>
<td>Diiododibromofluorescein</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>Ext. D &amp; C Blue No. 1</td>
<td>CL 52015</td>
<td>Methylene Blue</td>
<td></td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>Ext. D &amp; C Blue No. 4</td>
<td>CL 63010</td>
<td>Atizarin Saphirol</td>
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<td></td>
</tr>
<tr>
<td>23</td>
<td>Ext. D &amp; C Green No.1</td>
<td>CL 10020</td>
<td>Naphthol Green B</td>
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</tr>
<tr>
<td>24</td>
<td></td>
<td>CL 18055</td>
<td>Amidonaphthol Red 6 B</td>
<td></td>
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</tr>
<tr>
<td>25</td>
<td>Ext. D &amp; C Red No. 2</td>
<td>CL 16105</td>
<td>Pigment Scarlet NA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>26</td>
<td>Ext. D &amp; C Red No. 3</td>
<td>CL 45109</td>
<td>Violamine R</td>
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<td></td>
</tr>
<tr>
<td>27</td>
<td>Ext. D &amp; C Red No. 14</td>
<td>CL 12140</td>
<td>Oil Red XO</td>
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<tr>
<td>28</td>
<td>Ext. D &amp; C Red No. 15</td>
<td>CL 16155</td>
<td>Ponceau 3 R</td>
<td></td>
<td></td>
</tr>
<tr>
<td>29</td>
<td>Ext. D &amp; C Orange No. 3</td>
<td>CL 14600</td>
<td>Orange I</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30</td>
<td>Ext. D &amp; C Yellow No. 1</td>
<td>CL 13065</td>
<td>Metanil Yellow</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>Ext. D &amp; C Yellow No. 6</td>
<td>CL 14010</td>
<td>Dupont Yellow</td>
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<td></td>
</tr>
<tr>
<td>---</td>
<td>------------------------</td>
<td>----------</td>
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<tr>
<td>32</td>
<td>Ext. D &amp; C Yellow No. 9</td>
<td>CL 11380</td>
<td>Yellow AB</td>
<td></td>
<td></td>
</tr>
<tr>
<td>33</td>
<td>Ext. D &amp; C Yellow No. 10</td>
<td>CL 11390</td>
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<tr>
<td></td>
<td></td>
<td>CL 77266</td>
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</tr>
<tr>
<td>35</td>
<td>D &amp; C Orange No. 17</td>
<td>CL 12075</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>36</td>
<td>D &amp; C Red No. 8</td>
<td>CL 15585</td>
<td>Lake Red C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>37</td>
<td>D &amp; C Red No. 9</td>
<td>CL 15581:1</td>
<td>Lake Red CBA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>38</td>
<td>D &amp; C Red No. 19</td>
<td>CL 45170</td>
<td>Rhodamine</td>
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</tr>
<tr>
<td>39</td>
<td></td>
<td>CL 26105</td>
<td></td>
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<tr>
<td>40</td>
<td></td>
<td>CL 42555-1</td>
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<tr>
<td>41</td>
<td></td>
<td>CL 42555-2</td>
<td></td>
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<td>42</td>
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<td>CL 42535</td>
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<tr>
<td>43</td>
<td></td>
<td>CL 61544</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>44</td>
<td>D &amp; C Red No. 33 Zirconium Lake</td>
<td>CL 17200</td>
<td>Food Red 12</td>
<td></td>
<td></td>
</tr>
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</table>
### TABLE V - PERMISSIBLE COLOR ADDITIVES
LIST OF COLORANT RESTRICTED/ALLOWED FOR COSMETIC PRODUCTS

The following color additives are not to be incorporated in cosmetics for use in the area around in the eye.

<table>
<thead>
<tr>
<th>REF NO</th>
<th>FD &amp; C Designation</th>
<th>Color Index Number</th>
<th>Common Name</th>
<th>Uses and Restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F D &amp; C Green No. 3</td>
<td>CL 42053</td>
<td>Fast Green FCF</td>
<td>To color externally applied cosmetics</td>
</tr>
<tr>
<td>2</td>
<td>F D &amp; C Red No. 4</td>
<td>CL 14700</td>
<td>Ponceau SX</td>
<td>- do -</td>
</tr>
<tr>
<td>3</td>
<td>F D &amp; C Yellow No. 6</td>
<td>CL 15985</td>
<td>Sunset Yellow</td>
<td>- do -</td>
</tr>
<tr>
<td>4</td>
<td>D &amp; C Blue No. 4</td>
<td>CL 42090</td>
<td>Alphazunne PG</td>
<td>to color externally applied cosmetics</td>
</tr>
<tr>
<td>5</td>
<td>D &amp; C Brown No. 1</td>
<td>CL 20170</td>
<td>Resorcin Brown</td>
<td>to color externally applied cosmetics</td>
</tr>
<tr>
<td>6</td>
<td>D &amp; C Green No. 6</td>
<td>CL 61565</td>
<td>Quinizarine Green SS</td>
<td>- do -</td>
</tr>
<tr>
<td>7</td>
<td>D &amp; C Green No. 8</td>
<td>CL 59040</td>
<td>Pyranine</td>
<td>to color externally applied cosmetics</td>
</tr>
<tr>
<td>8</td>
<td>D &amp; C Orange No. 4</td>
<td>CL 15510</td>
<td>Orange II</td>
<td>to color externally applied cosmetics</td>
</tr>
<tr>
<td>9</td>
<td>D &amp; C Orange No. 5</td>
<td>CL 45370:1</td>
<td>Dibromofluorescin</td>
<td>to color externally applied cosmetics</td>
</tr>
<tr>
<td>10</td>
<td>D &amp; C Orange No. 10</td>
<td>CL 45425:1</td>
<td>Diiodofluorescin</td>
<td>to color mouthwashes &amp; dentitrites that are ingested cosmetics; to color lipstick and other lip cosmetics in amounts to exceeding 5% by weight of the finished product to color externally applied cosmetics</td>
</tr>
<tr>
<td>11</td>
<td>D &amp; C Orange No. 11</td>
<td>CL 45425</td>
<td>Erythrosine Yellowish NA</td>
<td></td>
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<tr>
<td>12</td>
<td>D &amp; C Red No. 6</td>
<td>CL 15850</td>
<td>Pigment Rubine</td>
<td>to color externally applied cosmetics</td>
</tr>
<tr>
<td>13</td>
<td>D &amp; C Red No. 7</td>
<td>CL 15850:1</td>
<td>Lithol Rubine BCA</td>
<td>to color externally applied cosmetics</td>
</tr>
<tr>
<td>14</td>
<td>D &amp; C Red No. 17</td>
<td>CL 26100</td>
<td>Sudan III</td>
<td>- do -</td>
</tr>
<tr>
<td>15</td>
<td>D &amp; C Red No. 21</td>
<td>CL 45380:2</td>
<td>Tetrabromofluorescien</td>
<td>to color cosmetics generally</td>
</tr>
<tr>
<td>16</td>
<td>D &amp; C Red No. 22</td>
<td>CL 45380</td>
<td>Eosin YS</td>
<td>- do -</td>
</tr>
<tr>
<td>17</td>
<td>D &amp; C Red No. 27</td>
<td>CL 45410:1</td>
<td>Tetrachlorotetramofluorescein</td>
<td>to color externally applied cosmetics</td>
</tr>
<tr>
<td>18</td>
<td>D &amp; C Red No. 28</td>
<td>CL 45410</td>
<td>Phloxine B</td>
<td>to color cosmetics generally</td>
</tr>
<tr>
<td>19</td>
<td>D &amp; C Red No. 30</td>
<td>CL 73360</td>
<td>Helindone Pink CH or VAT Red I</td>
<td>to color cosmetics generally</td>
</tr>
<tr>
<td>20</td>
<td>D &amp; C Red No. 31</td>
<td>CL 15800</td>
<td>Brillant Lake Red</td>
<td>- do -</td>
</tr>
<tr>
<td>21</td>
<td>D &amp; C Red No. 33 except</td>
<td>CL 17200</td>
<td></td>
<td></td>
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<tr>
<td>REF NO</td>
<td>FD &amp; C Designation</td>
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<td>Common Name</td>
<td>Uses and Restrictions</td>
</tr>
<tr>
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<td>--------------------</td>
<td>------------------------------------</td>
<td>-----------------------------------------------------</td>
</tr>
<tr>
<td>22</td>
<td>D &amp; C Red No. 34 and its Zr lake</td>
<td>CL 15880</td>
<td>Fast Acid Magenta</td>
<td>- do - to color externally applied cosmetics</td>
</tr>
<tr>
<td>23</td>
<td>D &amp; C Red No. 36</td>
<td>CL 12085</td>
<td>Deep Maroon; Fachon Maroon</td>
<td>- do - to color lipsticks and other lip cosmetics in amount not exceeding 3% expressed as pure dye by weight of each lipstick or other lip cosmetics, to color mouthwashes and dentrifices.</td>
</tr>
<tr>
<td>24</td>
<td>D &amp; C Violet No. 2</td>
<td>CL 60725</td>
<td>Chlorinated p-Nitroaniline Red</td>
<td>- do - to color externally applied cosmetics</td>
</tr>
<tr>
<td>25</td>
<td>D &amp; C Yellow No. 7</td>
<td>CL 45350</td>
<td>Fluorescein</td>
<td>- do - to color lipsticks and other lip cosmetics in amount not exceeding 3% expressed as pure dye by weight of each lipstick or other lip cosmetics; to color mouthwashes and dentrifices.</td>
</tr>
<tr>
<td>26</td>
<td>D &amp; C Yellow No. 8</td>
<td>CL 45350</td>
<td>Uranine</td>
<td>- do - to color externally applied cosmetics</td>
</tr>
<tr>
<td>27</td>
<td>D &amp; C Yellow No. 10</td>
<td>CL 47005</td>
<td>Quinoline Yellow WS</td>
<td>- do - to color externally applied cosmetics</td>
</tr>
<tr>
<td>28</td>
<td>D &amp; C Yellow No. 11</td>
<td>CL 47000</td>
<td>Quinoline Yellow</td>
<td>- do - to color externally applied cosmetics</td>
</tr>
<tr>
<td>29</td>
<td>Ext. D &amp; C Yellow No. 7</td>
<td>CL 10316</td>
<td>Naphthol Yellow</td>
<td>- do - to color externally applied cosmetics</td>
</tr>
<tr>
<td>30</td>
<td>Ext. D &amp; C Yellow No. 2</td>
<td>CL 60730</td>
<td>Alizuro Purple SS</td>
<td>- do - to color externally applied cosmetics</td>
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</tbody>
</table>

The following color additives may be incorporated in cosmetics for use in the area around the eye.

<table>
<thead>
<tr>
<th>REF NO</th>
<th>FD &amp; C Designation</th>
<th>Color Index Number</th>
<th>Common Name</th>
<th>Uses and Restrictions</th>
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</thead>
<tbody>
<tr>
<td>31</td>
<td>FD &amp; C Blue No. 1 and its Aluminum Lake</td>
<td>CL 42090</td>
<td>Brilliant Blue FCF</td>
<td>To color cosmetics generally including those applied in the area of the eye</td>
</tr>
<tr>
<td>32</td>
<td>FD &amp; C Red No. 40 and its Aluminum Lake</td>
<td>CL 46035</td>
<td>Allura Red</td>
<td>- do -</td>
</tr>
<tr>
<td>33</td>
<td>FD &amp; C Yellow No. 5 and its Aluminum Lake</td>
<td>CL 19140</td>
<td>Tartrazine</td>
<td>- do -</td>
</tr>
<tr>
<td>No.</td>
<td>Description</td>
<td>CL Number</td>
<td>Additional Information</td>
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<tr>
<td>-----</td>
<td>------------------------------------------------------------------------------</td>
<td>-----------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>34</td>
<td>D &amp; C Green No. 5 and its Aluminum Lake</td>
<td>CL 61570</td>
<td>Alizarin Cyanide Green F</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>CL 75120</td>
<td>- do -</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CL 75470</td>
<td>- do -</td>
<td></td>
</tr>
<tr>
<td>37</td>
<td></td>
<td>CL 75130</td>
<td>Bismuth Citrate</td>
<td></td>
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<tr>
<td></td>
<td>(CL 40800)</td>
<td>CL 75130</td>
<td>- do -</td>
<td></td>
</tr>
<tr>
<td>38</td>
<td></td>
<td>CL 75810</td>
<td>Disodium EDTA Copper</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CL 75810</td>
<td>- do -</td>
<td></td>
</tr>
<tr>
<td>39</td>
<td></td>
<td>CL 77400</td>
<td>Bronze Powder</td>
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<tr>
<td>40</td>
<td></td>
<td>CL 77400</td>
<td>Copper Powder</td>
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<tr>
<td></td>
<td></td>
<td>CL 77007</td>
<td>Ultramarines</td>
<td></td>
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<td></td>
<td></td>
<td>CL 77742</td>
<td>Manganese Violet</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CL 77947</td>
<td>Pigment Violet 16</td>
<td></td>
</tr>
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</table>

To color cosmetics, including those intended for use in the area of the eye.

To color externally applied cosmetics including those applied to the area of the eye.
<table>
<thead>
<tr>
<th></th>
<th>CL Code</th>
<th>Chemical Name</th>
<th>Restrictions</th>
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<tbody>
<tr>
<td>46</td>
<td>CL 77510</td>
<td>Zinc Oxide</td>
<td>- do -</td>
</tr>
<tr>
<td>47</td>
<td>CL 77820</td>
<td>Ferric Ferrocyanide, Prussian Blue</td>
<td>- do -</td>
</tr>
<tr>
<td>48</td>
<td></td>
<td>Silver</td>
<td>- do -</td>
</tr>
<tr>
<td>49</td>
<td></td>
<td>Caramel</td>
<td>to color fingernail polish at a level not to exceed 1% by weight of the final product</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lead Acetate</td>
<td>to color cosmetics generally including those applied to the area of the eye</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>to color cosmetics intended for coloring hair subject to the following restrictions:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1) the amount of lead acetate shall be such that the lead content calculated as lead (Pb) shall not exceed 0.6% (weight per volume);</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2) the label of the cosmetic shall bear the ff. Cautionary statement conspicuously displayed thereon: CAUTION: Contains lead acetate.</td>
</tr>
<tr>
<td>50</td>
<td>CL 77163</td>
<td>Bismuth Oxychloride</td>
<td>For external use only. Keep out of reach of children. Do not use on cut or abraded scalp. If skin Irritations, develop, discontinue use.</td>
</tr>
<tr>
<td>51</td>
<td></td>
<td>Guaiazulene</td>
<td>Do not use to color moustaches, eyelashes, eyebrows or hair on parts of the body other than the scalp. Do not get into eyes. Follow instructions carefully and wash hands thoroughly after use.</td>
</tr>
<tr>
<td>52</td>
<td>CL 75480</td>
<td>Henna</td>
<td>To color cosmetics including those intended for use in the area of the eye</td>
</tr>
<tr>
<td>53</td>
<td>CL 77499</td>
<td>Black Iron Oxides</td>
<td>To color externally applied cosmetics</td>
</tr>
<tr>
<td>54</td>
<td>CL 77492</td>
<td>Yellow Iron Oxides</td>
<td>To color hair only; it is not used in coloring eyelashes, eyebrows, or generally in the area of the eye. Label shall bear the following: “Do not use in cut or abraded scalp.”</td>
</tr>
<tr>
<td>55</td>
<td>CL 77491</td>
<td>Red Iron Oxides</td>
<td></td>
</tr>
<tr>
<td>56</td>
<td>CL 77491</td>
<td></td>
<td></td>
</tr>
<tr>
<td>57</td>
<td>CL 77520</td>
<td>Brown Iron Oxides</td>
<td>To color cosmetics including those intended for use in the area of the eye</td>
</tr>
<tr>
<td>58</td>
<td>CL 77289</td>
<td>Ferric Ammonium Ferrocyanide</td>
<td>- do -</td>
</tr>
<tr>
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<td></td>
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</tr>
<tr>
<td>---</td>
<td>---</td>
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</tr>
<tr>
<td>59</td>
<td>CL 75170</td>
<td>Chromium Hydroxide Green</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CL 77288</td>
<td>Guanine</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chromium Oxide Green</td>
<td></td>
</tr>
<tr>
<td>61</td>
<td>CL 77019</td>
<td>Pyrophillite</td>
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<tr>
<td></td>
<td>CL 77891</td>
<td>Mica</td>
<td></td>
</tr>
<tr>
<td>64</td>
<td>CL 77000</td>
<td>Titanium Dioxide</td>
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</tr>
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<td></td>
<td></td>
<td>Aluminum Powder</td>
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</tr>
<tr>
<td>65</td>
<td></td>
<td>Dihydroxyacetone</td>
<td></td>
</tr>
</tbody>
</table>

- do - 
- do - 

to color externally applied cosmetics including those intended for use in the area of the eye

- do - 

to color cosmetics generally

to color externally applied cosmetics including those intended for use in the area of the eye.

to color externally applied cosmetics

to color cosmetics including those applied to the area of the eye

- do - 

to color externally applied cosmetics including those intended for use in the area of the eye

for use in externally applied cosmetics “intended solely or in part to impart color to the human body.”
<table>
<thead>
<tr>
<th>Ref. No.</th>
<th>Designation</th>
<th>Color Index No.</th>
<th>Common Name</th>
<th>User/Restrictions</th>
<th>Allowed Until</th>
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<tbody>
<tr>
<td>1</td>
<td>Acid red 195</td>
<td></td>
<td></td>
<td>3</td>
<td>6-30-98</td>
</tr>
<tr>
<td>2</td>
<td>Aluminum, Zinc, Magnesium and Calcium Stearate</td>
<td></td>
<td></td>
<td>1</td>
<td>6-30-98</td>
</tr>
<tr>
<td>3</td>
<td>Anthocyanin</td>
<td></td>
<td></td>
<td>1 E163</td>
<td>6-30-98</td>
</tr>
<tr>
<td>4</td>
<td>Beet Red</td>
<td></td>
<td>1 E162</td>
<td>6-30-98</td>
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<tr>
<td>5</td>
<td>Bromclesol Green</td>
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<td>6-30-98</td>
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<tr>
<td>6</td>
<td>Bromthymol Blue</td>
<td></td>
<td>4</td>
<td>6-30-98</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Capsanthin/Capsorubin</td>
<td></td>
<td>1 E160C</td>
<td>6-30-98</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Lactoflavin/Riboflavin</td>
<td></td>
<td>1 E101</td>
<td>6-30-98</td>
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</tr>
<tr>
<td>9</td>
<td>Ext. DC Yellow No. 5</td>
<td>CL 10006</td>
<td>Pigment Green</td>
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<td>6-30-98</td>
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<tr>
<td>10</td>
<td>Ext. DC Orange No. 1</td>
<td>CI 11680</td>
<td>Hansa Yellow</td>
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<td>6-30-98</td>
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<td>Ext. DC Orange No. 1</td>
<td>CI 11725</td>
<td>10G</td>
<td>3</td>
<td>6-30-98</td>
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<tr>
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<td>Ext. DC Orange No. 1</td>
<td>CI 11920</td>
<td>Nansa Orange</td>
<td>4</td>
<td>6-30-98</td>
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<td>13</td>
<td>Ext. DC Orange No. 4</td>
<td>CI 12010</td>
<td>Sudan Orange G</td>
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<td>6-30-98</td>
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<tr>
<td>14</td>
<td>Ext. DC Orange No. 4</td>
<td>CI 12120</td>
<td>Fat Brown R</td>
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<td>6-30-98</td>
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<tr>
<td>15</td>
<td>Ext. DC Orange No. 4</td>
<td>CI 12370</td>
<td>Orange SS</td>
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<td>6-30-98</td>
</tr>
<tr>
<td>16</td>
<td>Ext. DC Orange No. 4</td>
<td>CI 12420</td>
<td>Permanent Red</td>
<td>4</td>
<td>6-30-98</td>
</tr>
<tr>
<td>17</td>
<td>Ext. DC Orange No. 4</td>
<td>CI 12480</td>
<td>F4RH</td>
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<td>6-30-98</td>
</tr>
<tr>
<td>18</td>
<td>Ext. DC Orange No. 4</td>
<td>CI 12490</td>
<td>Brown FG</td>
<td>1</td>
<td>6-30-98</td>
</tr>
<tr>
<td>19</td>
<td>Ext. DC Orange No. 4</td>
<td>CI 12700</td>
<td>Carmin FB</td>
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<td>6-30-98</td>
</tr>
<tr>
<td>20</td>
<td>Ext. DC Orange No. 4</td>
<td>CI 13015</td>
<td>Sudan Yellow</td>
<td>1</td>
<td>6-30-98</td>
</tr>
<tr>
<td>21</td>
<td>Ext. DC Orange No. 4</td>
<td>CI 14270</td>
<td>3G</td>
<td>1 E 013</td>
<td>6-30-98</td>
</tr>
<tr>
<td>22</td>
<td>Ext. DC Orange No. 4</td>
<td>CI 14720</td>
<td>Fast Yellow SX</td>
<td>1 E122</td>
<td>6-30-98</td>
</tr>
<tr>
<td>23</td>
<td>Ext. DC Orange No. 4</td>
<td>CI 14720</td>
<td>Chrysoine S</td>
<td>1 E122</td>
<td>6-30-98</td>
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<tr>
<td>24</td>
<td>Ext. DC Orange No. 4</td>
<td>CI 14815</td>
<td>Carmoisine</td>
<td>1 E125</td>
<td>6-30-98</td>
</tr>
<tr>
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<td>Wool Green BS</td>
<td>1 when used in lipstick the colouring agent is allowed only in free acid for and in a max. concentration of 1% 2 Not more than 1% 2-(6-hydroxy-3-OXO-3H-xanthen-9-yl) benzoic acid &amp; 2% 2-(bromo-6-hydroxy-3OXO-3H-xanthen-9-yl) benzoic acid</td>
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Uses and Restrictions:

1. Coloring agents which are permitted for all cosmetics goods.
2. Coloring agents which are permitted for all cosmetics goods, with the exception of eye area preparations.
3. Coloring agents which may only be used in cosmetic goods that do not come into contact with mucosa.
4. Coloring agents which may only be used in cosmetic goods intended to come into contact with the skin only briefly.

(1) Lakes or salts of these colouring agents using substances not prohibited under Table IX and strontium compounds except those listed in Table IX, are equally allowed.

(2) Coloring Agents whose number is preceded by the letter “E” in accordance with the EEC directive of 1962 concerning foodstuffs and coloring matters must fulfill the purity laid down in those directives.

(3) The insoluble barium, strontium and zirconium lakes, salts and pigments of those colouring agents shall also be permitted, they must pass the test for insolubility which will be determined by the procedure laid down in Article 8.
Sunscreen agents are substances which are specifically intended to filter certain UV rays in order to protect the skin from certain harmful effects of these rays. These sunscreen agents may be added to other cosmetic products within the limits and under the conditions laid down in this table. Other sunscreen agents used in cosmetic products solely for the purpose of protecting the products against UV rays are not included in this Table.

Table VII
Sunscreen Agents
List of Sunscreen Agents which cosmetic products may contain

<table>
<thead>
<tr>
<th>Ref. No.</th>
<th>Substance</th>
<th>Maximum Allowable Concentration</th>
<th>Limitation s and requirements</th>
<th>Conditions of use and warning which must be printed on the label</th>
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<tr>
<td>1</td>
<td>N,N,N-trimethyl-(2-oxoborn-3-ylidenemethyl) anilinium methyl sulphate (Camphor benzalkonium methosulfate)</td>
<td>15%</td>
<td>6%</td>
<td>This term sunscreen. When used anywhere in the labelling of a cosmetic product. Must be qualified by the following to describe the cosmetic benefit provided by the sunscreen: “This product contains a sunscreen that assists in protecting the (site of action) from damage by the sun.”</td>
</tr>
<tr>
<td>2</td>
<td>Homosalate (INN)</td>
<td>15%</td>
<td>8% (expressed as acid)</td>
<td>Prohibited in aerosols (sprays)</td>
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<tr>
<td>3</td>
<td>2-Phenyldibenzimidazole-5-sulphonic acid and its potassium, sodium and triethanolamine salts (Phenyldibenzimidazole sulphonic acid)</td>
<td>10%</td>
<td>5% (expressed as acid)</td>
<td>Contains oxybenzone (1)</td>
</tr>
<tr>
<td>4</td>
<td>1-(4-ter-butylphenyl)-3-(4-methoxyphenyl)propane-1,3-dione (Butyl methoxydibenzoyl methane) (Parsol 1789)</td>
<td>10%</td>
<td>3%</td>
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</tr>
<tr>
<td>5</td>
<td>2-Ethoxyethyl-p-methoxycinnamate (Cinoxate)</td>
<td>5%</td>
<td>10%</td>
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<tr>
<td>6</td>
<td>2,3-(1,4-Phenylenedimethyleldyne) bis (7,7-dimethyl-2-oxo-bicyclo-(2,2,1) heptane-1-methane-sulphonic acid) and its salts (Terephthalidene dicamphor sulfonic acid)</td>
<td>10%</td>
<td>3%</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>2-Ethylhexyl 4-dimethylaminobenzoate (Octyl dimethyl PABA)</td>
<td>5%</td>
<td>3%</td>
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<tr>
<td>8</td>
<td>2-Ethylhexyl 4-methoxycinnamate (Octyl methoxycinnamate)</td>
<td>3%</td>
<td>10%</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Zinc Oxide</td>
<td>3%</td>
<td>10%</td>
<td></td>
</tr>
</tbody>
</table>

(1) Not required if concentration is 0.5% or less and when it is used for product protection purpose.
<table>
<thead>
<tr>
<th>Ref. No.</th>
<th>Substance</th>
<th>Maximum Allowable Concentration</th>
<th>Limitations and Requirements and Conditions of use and Warning which must be printed on the label</th>
<th>Allowed Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ethoxylated-ethyl-4-amino benzoate (Ethoxylated-ethyl PABA)</td>
<td>10%</td>
<td>The term sunscreen when used anywhere in labelling of a cosmetic product must be qualified by the following to describe the cosmetic benefit provided by the sunscreen: “This product contains a sunscreen that assists in protecting the (site of action) from damage by the sun.”</td>
<td>12-31-97</td>
</tr>
<tr>
<td>2</td>
<td>2-Ethylhexyl salicylate (Octyl salicylate)</td>
<td>5%</td>
<td></td>
<td>12-31-97</td>
</tr>
<tr>
<td>3</td>
<td>Isopenyl-4-methoxycinnamate (Mixed Isomers)</td>
<td>10%</td>
<td></td>
<td>12-31-97</td>
</tr>
<tr>
<td>4</td>
<td>2-Hydroxy-4-methoxybenzophenone 5 sulphonic acid and sodium salt (Sulisobenzone and Sulisobenzone sodium)</td>
<td>6%</td>
<td></td>
<td>12-31-97</td>
</tr>
<tr>
<td>5</td>
<td>3-(4’ Methylbenzylidene)-d-1-camphor (4-Methylbenzylidene camphor)</td>
<td>6%</td>
<td></td>
<td>12-31-97</td>
</tr>
<tr>
<td>6</td>
<td>3-Benzylidene camphor</td>
<td>6%</td>
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<td>12-31-97</td>
</tr>
<tr>
<td>7</td>
<td>4-Isopropyl-dibenzoyl-methane</td>
<td>5%</td>
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<tr>
<td>8</td>
<td>4-Isopropylbenzul salicylate</td>
<td>4%</td>
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<td>12-31-97</td>
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<td>9</td>
<td>2,4,6 Triazinilone-(p-carbo-2’-ethylhexyl-1’-oxil)-1,3,5-triazine</td>
<td>5%</td>
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<td>12-31-97</td>
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<tr>
<td>10</td>
<td>Alpha-(2-Oxoborn-3-ylidone) Toluene-4-sulphonic acid and its salts (toluene sulfonic acid) (4-Methylbenzene sulfonic acid)</td>
<td>6% (expressed as acid) 2% (expressed as acid)</td>
<td></td>
<td>12-31-97</td>
</tr>
<tr>
<td>11</td>
<td>3-Imidazol-4-ylacrylic acid and its ethyl ester (Urocanic acid)</td>
<td>5%</td>
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<td>12-31-97</td>
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<tr>
<td></td>
<td>Substance Description</td>
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<td>1</td>
<td>N-5-Chlorobenzoxazol-2-ylacetamide</td>
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<td>2-Acetoxyethyltrimethylammonium hydroxide (acetylcholine and its salts)</td>
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<tr>
<td>3</td>
<td>Deanol aceglumate</td>
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<td>4</td>
<td>Spironolactone</td>
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<td>5</td>
<td>(4-(4-Hydroxy-3-iodophenoxy)-3,5-diodophenyl) acetic acid and its salts</td>
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<td>6</td>
<td>Methotrexate</td>
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<td>Aminocaproic acid and its salts</td>
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<tr>
<td>8</td>
<td>Cinchophen, its salts, derivatives and salts of these derivatives</td>
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<tr>
<td>9</td>
<td>Thyropropic acid and its salts</td>
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<tr>
<td>10</td>
<td>Trichloroacetic acid</td>
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<td>11</td>
<td>Anonitum napellus L. (leaves, roots and galenical preparations)</td>
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<td>12</td>
<td>Aconitine (principal alkaloid of aconitum napellus L.) and its salts</td>
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<td>13</td>
<td>Adonis vernalis L. and its preparations</td>
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<td>14</td>
<td>Epinephrine</td>
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<td>15</td>
<td>Rauwolfia serpentina alkaloids and its salts</td>
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<td>16</td>
<td>Alkyne alcohols, their esters, ethers and salts</td>
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<td>17</td>
<td>Isoprenaline</td>
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<td>18</td>
<td>Allyl isothiocyanate</td>
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<td>19</td>
<td>Alloclamide and its salts</td>
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<td>20</td>
<td>Nalorphine, its salts and ethers</td>
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<td>21</td>
<td>Sympathicomimetic amines acting on the central nervous system:</td>
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<td></td>
<td>Any substance contained in the first list of medicaments which are subject to medical prescription.</td>
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<td>Aniline, its salts and its halogenated and sulphonated derivatives</td>
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<td>23</td>
<td>Butoxycaïne and its salts</td>
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<td>24</td>
<td>Zoxazolamine</td>
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<td>25</td>
<td>Procaïnamide, its salts and derivatives</td>
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<td>26</td>
<td>Benzidine</td>
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<td>27</td>
<td>Tuaminoheptane, its isomers and salts</td>
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<td>Octodrine and its salts</td>
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<td>29</td>
<td>2-amino-1,2-bis (4-methoxyphenyl) ethanol and its salts</td>
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<td>30</td>
<td>1,3-dimethylpentylamine and its salts</td>
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<td>31</td>
<td>4-Aminosalicylic acid and its salts</td>
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<td>32</td>
<td>Toluidines, their isomers, salts and halogenated and sulphonated derivatives</td>
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<td>Xylidines, their isomers, salts and halogenated and sulphonated derivatives</td>
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<td>34</td>
<td>Imperatorin (9-(3-methylbut-2-enyloxy)furo(3,2-g)chromen-7-one)</td>
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<td>Ammi majus and its galenical preparations</td>
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<td>36</td>
<td>2,3-Dichloro-2-methylbutane</td>
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<td>37</td>
<td>Substances with androgenic effect</td>
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<td>38</td>
<td>Anthracene oil</td>
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<td>39</td>
<td>Antibiotics</td>
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<td>40</td>
<td>Antimony and its compounds</td>
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<td>41</td>
<td>Apocynum cannabinum L. and its preparations</td>
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<td>42</td>
<td>Apomorphine (R5,6,6a,7-tetrahydro-6-methyl-4H-dibenzo (de,g)-quinoline-10,11-diol) and its salts</td>
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<td>Arsenic and its compounds</td>
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<td>44</td>
<td>Atropine belladonna L. and its preparations</td>
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<td>45</td>
<td>Atropine, its salts and derivatives</td>
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<td>46</td>
<td>Barium salts with the exception of barium sulphate, barium sulphide under the conditions laid down in Table 1 and lakes, salts and pigments prepared from the colouring agents in Table V</td>
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<td>47</td>
<td>Benzene</td>
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<td>48</td>
<td>Benzimidazol-2(3H)-one</td>
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<td>49</td>
<td>Benzazepines and bezodiazepines</td>
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<td>50</td>
<td>1-Dimethylaminomethyl-1-methylpropyl benzoate (amylocaine) and its salts</td>
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<td>51</td>
<td>2,2,6-Trimethyl-4-piperidyl benzoate (benzamine) and its salts</td>
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<td>Name</td>
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<td>Isocarboxazid</td>
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<td>Bendroflumethiazide and its derivatives</td>
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<td>54</td>
<td>Beryllium and its compounds</td>
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<td>Bromine, elemental</td>
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<td>Bretylium tosilate</td>
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<td>Carbromal</td>
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<td>59</td>
<td>Brompheniramine and its salts</td>
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<td>60</td>
<td>Benzilonium bromide</td>
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<td>61</td>
<td>Tetrylammonium bromide</td>
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<td>Brucine</td>
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<td>Tetracine and its salts</td>
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<td>64</td>
<td>Mofebutazone</td>
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<td>Tolbutamide</td>
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<td>Carbutamide</td>
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<td>Phenylbutazone</td>
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<td>68</td>
<td>Cadmium and its compounds</td>
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<td>69</td>
<td>Cantharides, Cantharis vescicatori</td>
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<td>70</td>
<td>(1R, 2S)-Hexahydro-,2-dimethyl-3,6-epoxyphthalic anhydride (cantharidin)</td>
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<td>Phenprobamate</td>
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<td>Nitroderivatives of carbazale</td>
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<td>Carbon disulphide</td>
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<td>Catalase</td>
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<td>75</td>
<td>Cephaeline and its salts</td>
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<td>76</td>
<td>Chenopodium ambrosioides (essential oil)</td>
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<td>2,2,2-Trichloroethane-1,1-diol</td>
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<tr>
<td>78</td>
<td>Chlorine</td>
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<td>Chlorpropamide</td>
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<td>Diphenoxylate hydrochloride</td>
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<td>4-Phenylazophenylene-1,3-diamine citrate hydrochloride (chrysoidine citrate hydrochloride)</td>
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<td>Chloroxazone</td>
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<td>83</td>
<td>2-Chloro-6-methylpyrimidin-4-yldimethylamine (crimidine-ISO)</td>
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<td>Chlorprothixene and its salts</td>
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<td>Clofenamide</td>
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<td>N,N-bis (2-chloroethyl) methylamine N-oxide and its salts</td>
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<td>Chlormethine and its salts</td>
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<td>Cyclophosphamide and its salts</td>
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<td>Mannomustine and its salts</td>
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<td>Butanilicaine and its salts</td>
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<td>Chlormezanone</td>
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<td>Triparanol</td>
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<td>2-(2-(4-Chlorophenyl)-2-phenylacetyl)indan 1,3-dione (chlorophacinone-ISO)</td>
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<td>Chlorphenoxamine</td>
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<td>Phenaglycodol</td>
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<td>Chloroethane</td>
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<td>Chromium; chromic acid and its salts</td>
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<td>Claviceps purpurea Tul., its alkaloids and galenical preparations</td>
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<td>Conium maculatum L. (fruit, powder, galenical preparations)</td>
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<td>Glycyclamide</td>
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<td>Cobalt benzenesulphonate</td>
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<td>102</td>
<td>Colchicine, its salts and derivatives</td>
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<td>Colchicoside and its derivatives</td>
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<td>Colchicum autumnale L. and its galenical preparations</td>
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<td>105</td>
<td>Convallatoxin</td>
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<td>106</td>
<td>Anamirta cocculus L. (fruit)</td>
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<td>Croton tiglium (oil)</td>
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<td>108</td>
<td>1-Butyl-3-(n-crotonoylsulphanilyl) urea</td>
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<td>Compound Name</td>
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<td>Curare and curarine</td>
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<td>Synthetic curarizants</td>
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<td>Hydrogen cyanide and its salts</td>
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<td>112</td>
<td>2-alpha-Cyclohexylbenzyl (N,N,N',N'-tetraethyl) trimethylenediamine</td>
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<td>113</td>
<td>Cyclofenol and its salts</td>
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<td>114</td>
<td>Sodium hexacyclonate</td>
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<td>115</td>
<td>Hexapropymate</td>
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<td>116</td>
<td>Dextropropoxyphene</td>
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<td>117</td>
<td>O,O'-Diacetyl-N-allyl-N-normorphine</td>
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<td>118</td>
<td>Pipazetate and its salts</td>
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<td>119</td>
<td>5-(alpha B-Dibromophenetyl)-5-methylhydrantoin</td>
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<td>120</td>
<td>N,N'-Pentamethylenebis (trimethylammonium) salts, e.g. Pentamethonium</td>
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<td>121</td>
<td>N,N1-((Methylimino)diethylene)bis(ethyldimethylammonium) salts, e.g., azamethonium bromide</td>
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<td>122</td>
<td>Cyclarbamate</td>
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<td>123</td>
<td>Clofenotane; DDT (ISO)</td>
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<td>124</td>
<td>N,N'-Hexamethylenebis (trimethylammonium) salts, e.g. hexamethonium bromide*</td>
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<td>125</td>
<td>Dichloroethanes (ethylene chlorides)</td>
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<td>126</td>
<td>Dichloroethylenes (acetylene chlorides)</td>
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<td>127</td>
<td>Lysergide and its salts</td>
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<td>128</td>
<td>3-Diethylaminopropyl cinnamate</td>
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<td>129</td>
<td>O,O'-Dietyl 0-4nitrophenyl phosphorothiate (parathion-ISO)</td>
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<td>130</td>
<td>(Oxalylbisiminoethylene)bis((o-chlorobenzyl)diethylammonium) salts, e.g., ambenomium chloride</td>
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<td>131</td>
<td>Methylpyrilon and its salts</td>
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<td>132</td>
<td>Digitaline and all heterosides of Digitalis purpurea L.</td>
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<td>133</td>
<td>7-(2-Hydroxy-3-(2-hydroxyethyl)-N-methylamino)propyl)theophylline(xanthinol)</td>
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<td>134</td>
<td>Dioxethedrin and its salts</td>
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<td>135</td>
<td>Piprocurarium</td>
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<td>136</td>
<td>Propyphenazonate</td>
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<td>137</td>
<td>Tetrabenazine and its salts</td>
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<td>138</td>
<td>Propyphenazonate</td>
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<td>139</td>
<td>Tetrabenazine and its salts</td>
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<td>140</td>
<td>Captodiame</td>
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<td>141</td>
<td>Mefecloazine and its salts</td>
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<td>142</td>
<td>Dimethylamine</td>
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<td>143</td>
<td>1,1-Bis(dimethylaminomethyl) propyl benzoate (amydricaine, alypine) and its salts</td>
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<td>144</td>
<td>Methapyriline and its salts</td>
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<td>145</td>
<td>Metamfegramone and its salts</td>
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<td>146</td>
<td>Amitriptyline and its salts</td>
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<td>147</td>
<td>Metformin and its salts</td>
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<td>148</td>
<td>Isosorbide dinitrate</td>
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<td>149</td>
<td>Malononitrile</td>
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<td>Succinonitrile</td>
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<td>151</td>
<td>Dinitrophenol isomers</td>
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<td>Inproquone</td>
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<td>153</td>
<td>Dinemvamide and its salts</td>
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<td>154</td>
<td>Diphenylpyraline and salts</td>
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<td>Sulfinpyrazone</td>
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<td>156</td>
<td>N-(3-Carbamoyl-3,3-diphenylpropyl)-N,N-diisopropylmethylammonium salts, e.g., isopropamide iodide</td>
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<td>157</td>
<td>Benactyzine</td>
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<td>158</td>
<td>Benzatropine and its salts</td>
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<td>159</td>
<td>Cyclizine and its salts</td>
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<td>160</td>
<td>5,5-Diphenyl-4-imidazolidone</td>
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<td>Probenecid</td>
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<td>162</td>
<td>Disulfiram; thiram (ISO)</td>
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<td>163</td>
<td>Emetine, its salts and derivatives</td>
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<td>164</td>
<td>Ephedrine and its salts</td>
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<td>165</td>
<td>Oxanamid and its derivatives</td>
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<td>166</td>
<td>Eserine or physostigmine and its salts</td>
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<td>167</td>
<td>Esters of 4-aminobenzoic acid, with the free amino group, with the exception of ethoxylated ethyl-4-aminobenzoate and 2-ethylhexyl-4-dimethyl aminobenzoate</td>
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<td>168</td>
<td>Choline sales and their esters, e.g. choline chloride</td>
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<td>169</td>
<td>Caramiphen and its salts</td>
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<td>170</td>
<td>Diethyl 4-nitrophenyl phosphate</td>
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<td>171</td>
<td>Metethoheptazine and its salts</td>
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<td>172</td>
<td>Oxpheneridine and its salts</td>
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<td>173</td>
<td>Ethoheptazine and its salts</td>
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<td>174</td>
<td>Metheptazine and its salts</td>
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<td>175</td>
<td>Methylphenidate and its salts</td>
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<td>176</td>
<td>Doxylamine and its salts</td>
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<td>177</td>
<td>Tolboxane</td>
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<td>178</td>
<td>4-benzylxoyphenol, 4-methoxyphenol and 4-ethoxyphenol</td>
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<td>179</td>
<td>Parethoxycaine and its salts</td>
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<td>180</td>
<td>Fenozolone</td>
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<td>181</td>
<td>Glutethimide and its salts</td>
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<td>182</td>
<td>Ethylene oxide</td>
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<td>183</td>
<td>Bemegride and its salts</td>
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<td>184</td>
<td>Valnoctamide</td>
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<td>185</td>
<td>Haloperidol</td>
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<td>186</td>
<td>Paramethasone</td>
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<td>187</td>
<td>Fluaniocide</td>
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<td>188</td>
<td>Tiffuperidol</td>
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<td>189</td>
<td>Fluoresone</td>
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<td>190</td>
<td>Fluourouracil</td>
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<td>191</td>
<td>Hydrofluoric acid, its normal salts, its complexes and hydrofluorides with the exception of those given in Table 1</td>
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<td>192</td>
<td>Furfuryltrimethylammonium salts, e.g. furtrethionium iodide*</td>
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<td>193</td>
<td>Galantamine</td>
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<td>194</td>
<td>Progestogens</td>
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<td>195</td>
<td>1,2,3,4,5,6-Hexachlorocyclohexane (BHC-ISO) (lindane)</td>
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<td>196</td>
<td>(IR,4S,5R,8S)-1,2,3,4,10,10-Hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octa-hydro-1,4,5,8-dimethanonaphthalene (endrin-ISO)</td>
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<td>197</td>
<td>Hexachloroethane</td>
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<td>198</td>
<td>(IR,4S,5R,8S)-1,2,3,4,10,10-Hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-hexahydro-1,4,5,8-dimethanonaphthalene (isodrin-ISO)</td>
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<td>199</td>
<td>Hydrastine, hydrastanine and their salts</td>
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<td>200</td>
<td>Hydrazides and their salts</td>
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<td>201</td>
<td>Hydrazine, its derivatives and their salts</td>
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<td>202</td>
<td>Octamoxin and its salts</td>
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<td>203</td>
<td>Warfarin and its salts</td>
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<td>204</td>
<td>Ethyl bis (4-hydroxy-2-oxo-1-benzopyran-3-yl) acetate and salts of the acid</td>
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<td>205</td>
<td>Methocarbamol</td>
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<td>206</td>
<td>Propylnitrate</td>
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<td>207</td>
<td>4,4'-Dihydroxy-3,3'-(3-methylthiopropylidene) dicoumarin</td>
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<td>208</td>
<td>Fenadiazole</td>
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<td>209</td>
<td>Nitroxoline and its salts</td>
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<td>210</td>
<td>Hyoscymamine, its salts and derivative</td>
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<td>211</td>
<td>Hyoscyamus niger L. (leaves, seeds, powder and galenical preparations)</td>
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<td>212</td>
<td>Pemoline and its salts</td>
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<td>213</td>
<td>Iodine</td>
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<td>214</td>
<td>Demethylenebis (trimethylammonium) salts, e.g. decamethonium bromide</td>
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<td>215</td>
<td>Ipecacuanha (Cephaelis ipecacuanha Brot. And related species) roots, powder and galenical preparations</td>
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<td>216</td>
<td>(2-Isopropylpent-4-enyl) urea (apronalide)</td>
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<td>217</td>
<td>Alpha-santonin ((3S, 5aR, 9bS)-3,3a,4,5,5a,9b-hexahydro-3, 5a, 9-trimethyl-naphto (1,2-b) furan-2,8-dione</td>
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<td>218</td>
<td>Lobelia inflata L. and its galenical preparations</td>
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<td>219</td>
<td>Lobeline and its salts</td>
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<td>Barbiturates</td>
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<td>221</td>
<td>Mercury and its compounds</td>
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<td>222</td>
<td>3,4,5-Trimethoxyphenethylamine and its salts</td>
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<td>223</td>
<td>Metaldehyde</td>
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<td>224</td>
<td>2-(4-Allyl-2-methoxyphenoxy)-N,N-diethylacetamide and its salts</td>
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<td>Coumetarol</td>
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<td>Dextromethorphan and its salts</td>
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<td>227</td>
<td>2-Methylheptylamine and its salts</td>
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<td>228</td>
<td>Isomethyptene and its salts</td>
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<td>229</td>
<td>Mecamylamine</td>
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<td>Guaifenesin</td>
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<td>Dicoumarol</td>
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<td>232</td>
<td>Phenmetrazine, its derivatives and salts</td>
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<td>233</td>
<td>Thiamazole</td>
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<td>234</td>
<td>3,4-Dihydro--methoxy-2-methyl-4-phenyl-2H, 5H, pyrano(3,2-c)-(1) benzopyran-5-one (cyclocoumarol)</td>
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<td>Carisoprodol</td>
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<td>Meprobamate</td>
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<td>237</td>
<td>Tefazoline and its salts</td>
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<td>238</td>
<td>Arecoline</td>
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<td>Poldine metilsulfate</td>
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<td>Hydroxyzine</td>
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<td>241</td>
<td>2-Naphthol</td>
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<td>242</td>
<td>1-and 2-Naphthylamines and their salts</td>
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<td>243</td>
<td>3-(1-Naphthyl)-4-hydroxycoumarin</td>
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<td>244</td>
<td>Naphazoline and its salts</td>
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<td>245</td>
<td>Neostigmine and its salts (e.g. neostigmine bromide)</td>
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<td>246</td>
<td>Nicotine and its salts</td>
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<td>247</td>
<td>Amyl nitrtes</td>
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<td>248</td>
<td>Inorganic nitrates, with the exception of sodium nitrite</td>
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<td>Nitrostibenes, their homologues and their derivatives</td>
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<td>Noradrenaline and its salts</td>
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<td>Noscapine and its salts</td>
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<td>Strophantus species and their galenical preparations</td>
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<td>Veratrum Spp. And their preparations</td>
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<td>Benzoates of 4-hydroxy-3-methoxycinnamyl alcohol except for normal content in natural essences used</td>
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<td>Furo (3,2-g) chromen-7-one and its alkyl-substituted derivatives (e.g., trioxysalan and 8-methoxypsoralen), except for normal content in natural essences used</td>
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<td>Oil from the seeds of Laurus nobilis L.</td>
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<td>Safrole except for normal content in the natural essences used and provided the concentration does not exceed: 100 ppm in the finished product 50 ppm in products for dental and oral hygiene, and provided that Safrole is not present in toothpastes intended specifically for children</td>
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<td>4- methyl-m-phenylenediamine and its salts</td>
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<td>Aristolochic acid and its salts</td>
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<td>2,6-Dimethyl-1,3-dioxan-4-yacetate (Dimethoxane)</td>
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<td>6-(Piperidinyl)-2,4-pyrimidinediamine-3-oxide (Minoxidil) and its salts and derivatives</td>
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<td>Phytolacca Spp. And their preparations</td>
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<td>Tretinoin (retinoic acid and its salts)</td>
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<td>4-Mehoxy-m-phenylenediamine (2,4-diaminoanisole) and their sulfate salts</td>
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<tr>
<td>382</td>
<td>Amyl 4-dimethylaminobenzoate, mixed isomers</td>
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<td></td>
<td>(Padimate A (INN))</td>
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<tr>
<td>383</td>
<td>Benzoyl peroxide</td>
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<td>384</td>
<td>2-Amino-4-nitrophenol</td>
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<td>385</td>
<td>2-Amino-5-nitrophenol</td>
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<tr>
<td>386</td>
<td>11-alpha-Hydroxy-4-ene-3,20-dione and its</td>
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<tr>
<td></td>
<td>esters</td>
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<tr>
<td>387</td>
<td>Colouring agent Cl 42640</td>
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<td>388</td>
<td>Colouring agent Cl 42535</td>
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<td>389</td>
<td>Colouring agent Cl 61554</td>
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<tr>
<td>390</td>
<td>Antiandrogens with steroid structure</td>
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<tr>
<td>391</td>
<td>Zirconium and its compounds, with the</td>
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<tr>
<td></td>
<td>exception of the complexes under table 1 of</td>
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<tr>
<td></td>
<td>zirconium lakes, salts and pigments of</td>
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<td></td>
<td>colouring agents listed in table V and VI</td>
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<td>392</td>
<td>Thyrothricine</td>
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<tr>
<td>393</td>
<td>Acetonitrile</td>
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<tr>
<td>394</td>
<td>Tetrahydrozoline and its salts</td>
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<tr>
<td>395</td>
<td>Hydroxy-8-quinoline and its sulphate, except</td>
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<td></td>
<td>for the uses provided for in table 1</td>
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<tr>
<td>396</td>
<td>Dithio-2,2'-bipyridine-dioxide 1,1'</td>
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<td></td>
<td>(additive with the trihydrated magnesium)</td>
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<tr>
<td>397</td>
<td>Colouring agent Cl 12075 and its lakes,</td>
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<tr>
<td></td>
<td>pigments and salts</td>
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<td>398</td>
<td>Colouring agent Cl 45170 and Cl 45170:1</td>
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<tr>
<td>399</td>
<td>Lidocaine</td>
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<td>400</td>
<td>1,2-Epoxybutane</td>
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<td>401</td>
<td>Colouring agent Cl 15585</td>
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<tr>
<td>402</td>
<td>Strontium lactate</td>
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<td>403</td>
<td>Strontium nitrate</td>
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<td>404</td>
<td>Strontium polycarboxylate</td>
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<td>405</td>
<td>Pramocaine</td>
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<tr>
<td>406</td>
<td>4-Ethoxy-m-phenylenediamine and its salts</td>
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<tr>
<td>407</td>
<td>2,4-Diaminophenylethanol and its salts</td>
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<td>408</td>
<td>Catechol</td>
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<tr>
<td>410</td>
<td>Nitrosamines</td>
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<tr>
<td>411</td>
<td>Secondary dialkanoamines</td>
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<td>412</td>
<td>4-Amino-2-nitrophenol</td>
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<tr>
<td>413</td>
<td>2-Methyl-m-phenylenediamine</td>
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