Council of the
European Union

**Brussels, 13 January 2016**
**(OR. en)**

**5215/16**
**ADD 1**

**COMPET 8**
**ENV 11**
**CHIMIE 1**
**MI 9**
**ENT 5**
**SAN 7**
**CONSOM 3**

**COVER NOTE**

| | |
|---|---|
| From: | European Commission |
| date of receipt: | 12 January 2016 |
| To: | General Secretariat of the Council |
| No. Cion doc.: | D041721/03 ANNEX |
| Subject: | ANNEX to the COMMISSION REGULATION (EU) …/… of XXX amending Annexes VII and VIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards skin corrosion/irritation, serious eye damage/eye irritation and acute toxicity |

Delegations will find attached document D041721/03 ANNEX.

Encl.: D041721/03 ANNEX

**EN**

**ANNEX**

Point 8.1. of Annex VII shall be replaced by the following:

| | |
|---|---|
| "8.1. Skin corrosion/ irritation | 8.1. The study/ies do(es) not need to be conducted if:<br><br>— the substance is a strong acid (pH ≤ 2,0) or base (pH ≥ 11,5) and the available information indicates that it should be classified as skin corrosion (Category 1), or<br><br>— the substance is spontaneously flammable in air or in contact with water or moisture at room temperature, or<br><br>— the substance is classified as acute toxicity by the dermal route (Category 1), or<br><br>— an acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level (2 000 mg/kg body weight).<br><br>If results from one of the two studies under points 8.1.1. or 8.1.2. already allow a conclusive decision on the classification of a substance or on the absence of skin irritation potential, the second study need not be conducted. |
| 8.1.1. Skin corrosion, *in vitro* | |
| 8.1.2. Skin irritation, *in vitro* " | |

Point 8.2. of Annex VII shall be replaced by the following:

| | |
|---|---|
| "8.2. Serious eye damage/eye irritation | 8.2. The study/ies do(es) not need to be conducted if:<br>— the substance is classified as skin corrosion, leading to classification as serious eye damage (Category 1), or<br>— the substance is classified as skin irritation and the available information indicates that it should be classified as eye irritation (Category 2), or<br>— the substance is a strong acid (pH ≤ 2,0) or base (pH ≥ 11,5) and the available information indicates that it should be classified as serious eye damage (Category 1), or<br>— the substance is spontaneously flammable in air or in contact with water or moisture at room temperature. |
| 8.2.1. Serious eye damage/ | 8.2.1. If results from a first *in vitro* study do not allow a |

| | |
|---|---|
| eye irritation, *in vitro* | conclusive decision on the classification of a substance or on the absence of eye irritation potential, (an)other *in vitro* study/ies) for this endpoint shall be considered." |

Point 8.1. of Annex VIII shall be replaced by the following:

| | |
|---|---|
| "8.1. Skin corrosion/ irritation | 8.1. An *in vivo* study for skin corrosion/irritation shall be considered only if the *in vitro* studies under point 8.1.1. and 8.1.2. in Annex VII are not applicable, or the results of these studies are not adequate for classification and risk assessment.<br><br>The study does not need to be conducted if:<br>— the substance is a strong acid (pH ≤ 2,0) or base (pH ≥ 11,5), or<br>— the substance is spontaneously flammable in air or in contact with water or moisture at room temperature, or<br>— the substance is classified as acute toxicity by the dermal route (Category 1), or<br>— an acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level (2 000 mg/kg body weight)." |

Point 8.2. of Annex VIII shall be replaced by the following:

| | |
|---|---|
| "8.2. Serious eye damage/eye irritation | 8.2. An *in vivo* study for eye corrosion/irritation shall be considered only if the *in vitro* study(ies) under point 8.2.1. in Annex VII are not applicable, or the results obtained from these study(ies) are not adequate for classification and risk assessment.<br><br>The study does not need to be conducted if:<br>— the substance is classified as skin corrosion, or<br>— the substance is a strong acid (pH ≤ 2,0) or base (pH ≥ 11,5), or<br>— the substance is spontaneously flammable in air or in contact with water or moisture at room temperature." |

Point 8.5. of Annex VIII shall be replaced by the following:

| | |
|---|---|
| "8.5. Acute toxicity | 8.5. The study/ies do(es) not generally need to be conducted if:<br><br>— the substance is classified as skin corrosion. |

| | |
|---|---|
| | In addition to the oral route (Annex VII, 8.5.1.), for substances other than gases, the information mentioned under 8.5.2. to 8.5.3. shall be provided for at least one other route. The choice for the second route will depend on the nature of the substance and the likely route of human exposure. If there is only one route of exposure, information for only that route needs to be provided. |
| 8.5.2. By inhalation | 8.5.2. Testing by the inhalation route is appropriate if exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size. |
| 8.5.3. By dermal route | 8.5.3. Testing by the dermal route is appropriate if:<br><br>(1) inhalation of the substance is unlikely; and<br><br>(2) skin contact in production and/or use is likely; and<br><br>(3) the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin.<br><br>Testing by the dermal route does not need to be conducted if:<br><br>- the substance does not meet the criteria for classification as acute toxicity or STOT SE by the oral route and<br><br>- no systemic effects have been observed in *in vivo* studies with dermal exposure (e.g. skin irritation, skin sensitisation) or, in the absence of an *in vivo* study by the oral route, no systemic effects after dermal exposure are predicted on the basis of non-testing approaches (e.g. read across, QSAR studies). " |