
Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EU) No 283/2013. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

ANNEX

PART A

CHEMICAL ACTIVE SUBSTANCES

SECTION 5

Toxicological and metabolism studies

5.2. Acute toxicity

5.2.7. Phototoxicity

The study shall provide information on the potential of certain active substances to induce cytotoxicity in combination with light, for example active substances that are phototoxic *in vivo* after systemic exposure and distribution to the skin, as well as active substances that act as photoirritants after dermal application. A positive result shall be taken into account when considering potential human exposure.

Circumstances in which required

The *in vitro* study shall be required where the active substance absorbs electromagnetic radiation in the range 290-700 nm and is liable to reach the eyes or light-exposed areas of skin, either by direct contact or through systemic distribution.

If the Ultraviolet/visible molar extinction/absorption coefficient of the active substance is less than $10 \text{ L} \times \text{mol}^{-1} \times \text{cm}^{-1}$, no toxicity testing is required.

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Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by [S.I. 2019/556 reg. 21\(4\)](#)
- Annex Pt. A s. 8 word omitted by [S.I. 2019/556 reg. 21\(5\)\(b\)\(xiv\)](#)
- Annex Pt. A s. 1 point 1.4 word substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 176(2)(a)(i) by [S.I. 2020/1567 Sch. 2 para. 61](#)
- Annex Pt. A s. 1 point 1.4.1 word substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 176(2)(b) by [S.I. 2020/1567 Sch. 2 para. 61](#)
- Annex Pt. B s. 9 words omitted by [S.I. 2019/556 reg. 21\(5\)\(c\)\(vi\)](#)
- Art. 1(1) Art. 1 renumbered as Art. 1(1) by [S.I. 2019/556 reg. 21\(2\)\(a\)](#)
- Art. 1(2) inserted by [S.I. 2019/556 reg. 21\(2\)\(b\)](#)