

UK/SI proposal - Using Annex II of CLP to address 'Particle Toxicity'

Background

A previous paper from the UK (CA/MS/07/2018) explored how an Annex VI entry for titanium dioxide might be formulated to cover 'particle toxicity'. Several of the ideas presented in that paper were subsequently picked up by the Commission in CA/45/2018 discussed at CARACAL on 12 June.

A joint paper by Slovenia and the UK (CA/MS/48/2018) noted that several important issues remained open, including effective and meaningful communication of hazard for 'particle toxicity'.

In the discussion at CARACAL several Member States noted that even with the best efforts so far, it is proving difficult to incorporate 'particle toxicity' in an effective way using a substance specific entry in Annex VI, notwithstanding the use of several notes both for titanium dioxide and for mixtures containing it.

In CARACAL on 12 June and in the REACH Committee the following day, several delegations noted the potential advantages of using Annex II of CLP.

Proposal

The Annex to this paper sets out initial ideas on how the introduction of a new Part 6 in CLP Annex II could provide effective hazard communication for 'particle toxicity' without the complications and unintended consequences arising from Annex VI entries. UK/SI considers the approach offers a number of advantages:

- The proposal addresses directly in CLP the general concern of 'particle toxicity', as the issue is wider than titanium dioxide and extends to all poorly soluble low toxicity substances (PSLTs) in the form of a powder or dust.
- The proposal provides more meaningful hazard communication for 'particle toxicity' than the hazard statement H351i. For workplace use the phrase 'Warning! Contains respirable dust' also provides a link with existing national occupational exposure limits for respirable dust, and in future with any indicative occupational exposure limit value at EU level.
- It also addresses concerns for consumers and for professional users where these are not covered by existing national occupational exposure limits for dust.
- The scope of PSLTs in scope of Annex II is explicit and can easily be extended in an ATP process. If the proposal were adopted, in future RAC would have the option of recommending an entry in Part 6 of Annex II to CLP.
- If/when the inclusion of 'particle toxicity' in the GHS is clarified at UN level, the provisions introduced in Part 6 of Annex II to CLP can be easily aligned.
- The proposal avoids unintended and unnecessary downstream effects. For example, we understand classification of TiO₂ as carc cat 2 in Annex VI would trigger hazardous waste requirements for standard emulsion paints containing titanium dioxide regardless of any Notes excluding classification of liquid or solid mixtures.
- Effective hazard communication is achieved without prejudicing the important CLP principle that hazard classification applies to all forms of a substance or mixture as placed on the market and in which it can reasonably be expected to be used.
- By requiring supplemental information on labels for mixtures containing PSLTs the criterion for triggering a safety data sheet on request under REACH Article 31(3)(a) is met, as the mixture contains at least one substance posing human health hazards.

Annex – Proposal for addressing Particle Toxicity in Annex II of CLP

ANNEX II

SPECIAL RULES FOR LABELLING AND PACKAGING OF CERTAIN SUBSTANCES AND MIXTURES

This Annex consists of ~~5~~ 6¹ parts:

- Part 1 contains special rules for the labelling of certain classified substances and mixtures.
- Part 2 sets out rules for additional hazard statements to be included on the label of certain mixtures.
- Part 3 sets out special rules for packaging.
- Part 4 sets out a special rule for the labelling of plant protection products.
- Part 5 sets up a list of hazardous substances and mixtures to which Article 29(3) applies.
- **Part 6 sets out special rules for the labelling of poorly soluble low toxicity substances and mixtures containing them.**

The following text in Annex II would all be new:

PART 6: SPECIAL RULES FOR THE LABELLING OF POORLY SOLUBLE LOW TOXICITY SUBSTANCES AND MIXTURES CONTAINING THEM

6.1 This part applies to substances listed in 6.2 below characterised as poorly soluble low toxicity (PSLT), and to mixtures containing such substances.

6.2 Substances characterised as PSLT are:

- Titanium dioxide (CAS 13463-67-7)
- [others to be added over time]

6.3 The label on the packaging of:

- (a) A substance listed in 6.2 that is placed on the market as a powder or dust containing free respirable particles of diameter $\leq 10 \mu\text{m}$; or
- (b) A mixture placed on the market as a powder or dust and containing 1% w/w or more of free particles of a substance in (a) above

shall bear the statement:

EUHXXX – ‘Warning! Contains respirable dust. Follow safety instructions’.

6.4 For mixtures in 6.3(b) that are not otherwise classified as hazardous, and for substances in 6.3(a), the label on the packaging shall also bear the statement:

EUH210 – ‘Safety data sheet available on request’.

¹ Corresponding changes are needed in Article 25, but this can also be achieved by Adaptation to Technical Progress.

6.5 Notwithstanding 6.1 to 6.4 above, where the substance listed in 6.2 is in the form of fibres (with diameter $< 3\mu\text{m}$, length $> 5\mu\text{m}$ and aspect ratio $\geq 3:1$), or where there is reason to believe it has other hazardous properties than 'particle toxicity', e.g. because of surface coatings, its hazardous properties and relevant routes of exposure shall be evaluated in accordance with CLP Title II. Where the evaluation shows it has other hazards the substance, and mixtures containing it, shall be classified and labelled accordingly.