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## Statement on Imiprothrin CLH Proposal from UK eCA

### **Hypoplasia of the Nasal Bone in Rabbits**

Ossification of non-weight bearing bones is dependent on the maturity of the organs that are surrounded. In underdeveloped foetuses ossification of calvarial bones may be delayed until the brain reaches a specific level of maturity, at the time of or shortly after birth.

Alizarin Red S staining in small foetuses is often weak and inaccurate reporting of hypoplastic frontal bone may occur. A more accurate description is '*decreased ossification*' or '*developmental delay*'. It is popular opinion of EU experts and regulators that incomplete ossification represents a variation (Solecki *et al.* 2001).

Given the above and that findings were seen only in foetuses of Does that experienced significant maternal toxicity, decreased ossification should not provide a basis for classification.

### **27 Presacral Vertebrae in Rabbits**

The finding of 27 presacral vertebrae in rabbit foetuses was not found in numbers of statistical significance. The percentages of this finding in the dose litters fall within the laboratories historic control data range at doses below 30 mg/kg/day, and only by 0.7% difference in one of two 30 mg/kg/day dose groups. The second group to be administered this dose were clearly within the historical data range.

At other dose levels the finding is still seen within the range of normal variability observed in the test species, and is a relatively common finding without adverse effect on survival or health of rabbits. Evidence of maternal toxicity was seen in Does administered with doses of 300 mg/kg/day. Therefore the finding of 27 presacral vertebrae should not provide a basis for classification.

In view of the above, imiprothrin should not therefore be classified with the hazard statement H361d (Suspected of damaging the unborn child) and associated pictogram GHS08.

### **Reference**

Solecki R, Bergmann B, Bürgin H, Buschmann J, Clark R, Druga A, Van Duijnhoven EAJ, Duverger M, Edwards J, Freudenberger H, Guittin P, Hakaite P, Heinrich-Hirsch B, Hellwig J, Hofmann T, Hübel U, Khalil S, Klaus A-M, Kudicke S, Lingk W, Meredith T, Moxon M, Müller S, Paul M, Paumgarten F, Röhrdanz E, Pfeil R, Rauch-Ernst M, Seed J, Spezia F, Vickers C, Woelffel B, Chahoud I.. 2003. Harmonization of rat foetal external and visceral terminology and classification. Report of the Fourth Workshop on the Terminology in Developmental Toxicology, Berlin, 18–20 April 2002. *Reproductive Toxicology* 17: 625–637.

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