Exposure to alphachloralose in France and its overseas territories

Alphachloralose is an active substance approved as a PT 14 (rodenticide) biocide on 01/07/2011. However, this substance is no longer authorised in Europe as a plant protection active substance.

Alphachloralose is used in commercial preparations, but was also available over the counter in pharmacies in the French Caribbean as officinal preparations of 20-40% in lard, dispensed in 60-100g tubs for use as a rodenticide. A study carried out at the Pointe-à-Pitre University Hospital over the period 2000-2006 found many serious poisonings.

The clinical symptoms of acute alphachloralosis poisoning are well documented in humans. The time to onset of the first signs may vary from a few minutes (for massive doses) to a few hours after ingestion. The clinical signs are mainly neurological, combining consciousness disorders and motor hyperexcitability (focal and generalised myoclonus), often accompanied by salivary and bronchial hypercrinia, which can lead to respiratory distress.

As part of the regulatory assessment of commercial rodenticide products containing alphachloralose, ANSES required a detailed description of the human poisoning cases involving this substance that occurred in France.

The Agency therefore asked the network of poison control centres (PCCs) to study the cases of human exposure to alphachloralose recorded in their information system, in metropolitan France and the overseas territories. The aim was to describe exposure in terms of incidence, circumstances, products, severity and geographical distribution, and then to compare this information with the situation in the overseas territories, in order to confirm whether or not the latter were more affected due to local practices.

A retrospective study was conducted to analyse exposure to alphachloralose preparations, collected by French PCCs in the National Database of Poisoning Cases (BNCI) from 1 July 1999 to 31 December 2012 inclusive.

One thousand and seventy-one dossiers were collected over this period, with the number of annual exposures varying from 63 to 108 cases per year.

The poisonings were symptomatic and with a causality between the exposure agent(s) and the observed adverse effects non-null in more than half of the cases (n=537). A third of cases were serious (n=348), with deaths being observed in 2% of cases (n=21). The majority of people exposed were adults (61%), in contrast to other studies where children can account for 80% of accidental poisoning cases.

Accidental exposures, which represented 48% of cases, were symptomatic in 17% of cases (n=87) and serious in about 2% of cases (n=12), while no deaths were reported.

Exposure was intentional in more than 52% of cases (n=539), symptomatic in more than 81% of these cases (n=437), serious in almost 61% and 19 deaths were recorded. Note that the percentage of exposure with suicidal intent was much higher with this agent than with all the other exposure cases recorded in the BNCI, with 52% versus 15% of cases, respectively.

Single-agent suicidal poisonings (360 cases) were serious even when the presumed ingested dose was low, since 41% of patients in whom this dose was less than 3 grams had serious symptoms. This is consistent with the low toxic dose of the substance.

Two chronic intentional exposures resulting in multiple seizure episodes were noted.

1.Biocidal products are governed by Regulation (EU) No 528/2012. They are preparations of active substances for domestic or industrial use. These products include household disinfectants, insecticides and other products designed to eliminate, destroy or repel pests (fungi, bacteria, viruses, rodents, insects) by chemical or biological action.
2. Plant protection substances and products are governed by Regulation (EC) No 1107/2009. They are preparations intended to protect plants and crop products, preserve plant products and destroy undesirable plants. They are pesticides, a category that also includes biocides

The focus on the French overseas territories showed an incidence of 53.4 cases/10^7 person-years [45.1-62.8], while the incidence for France as a whole was 16.3 per 10^7 person-years. These exposures were symptomatic slightly less often (41.8% versus 50.1%) but the proportion of severe cases (32%) remained similar to that in the national study (whole France) (33%). There were an equivalent number of accidental and intentional exposure cases (n=72 versus n=72). The idea of preparation on a carrier food (bread, flour, tomato, cheese, biscuit, lard) featured in almost 40% of accidental exposure cases (n=28/72). In 7% of cases (n=5) the preparation was officinal.

Cases of exposure to alphachloralose were characterised by the frequency, products involved and severity of suicide attempts, even when small amounts were ingested. Accidental poisonings, although less often serious, sometimes involved small quantities, reflecting the high toxicity of this substance.

The marketing of alphachloralose products is currently subject to "biocide" regulations. Following this study and in order to prevent such accidents, the Ministry of Health referred the matter to the National Council of the Order of Pharmacists, to remind them that since alphachloralose is no longer listed in the Pharmacopoeia, pharmacists are no longer authorised to prepare or sell alphachloralose products unless they comply with the biocide regulations, which ensure safe use: concentration < 40 g/kg in tamper-proof bait boxes.

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