



TOXICOLOGICAL REVIEW

OF

2PURE

Prepared for

2pure Products



Toxicological review of 2Pure

2Pure is a biocidal product which may be used as an odour eliminator and cleaner for use around pets and people. For example, it may be sprayed on dog beds and left to dry off, on the seats of cars to get rid of smell and bacteria, in hutches to get rid of bacteria and odour. It may also be used in industrial settings such as sewage works, landfill sites or transfer stations, with or without the inclusion of fragrances. In such spray applications it is used at high dilutions (minimum 1 : 100 or 500 in water); droplet size is understood to be 50 microns. In a liquid non-spray form, it may be used as a patio and kennel cleaner to wash dog mess away. It may also be used as a general cleaner in hair salons and to eliminate perm solution odours, in care and nursing homes as a spray for cleaning and odour removal and generally as a cleaner and odour eliminator on carpets and surfaces.

A toxicological review and assessment of the 2Pure formulation has been undertaken by use of published literature and official guidelines and directives, including the Biocidal Products Directive (BPD; Directive 98/8/EC, February 1998). Where possible, the review of each ingredient has taken into account the areas of toxicological concern given in the BPD. This review considered the undiluted product and a 50% dilution.

The principal human exposure targets to be considered are professional users and members of the general public (consumers). Other exposure targets include dogs, cats, rabbits and, potentially, other animal species and, in a more general sense, the environment in respect of potential adverse ecotoxicological effects that the product may engender. Exposure to the product in the case of users or consumers would be expected to be principally dermal, with the potential for some inhalation into the upper respiratory tract if the product is sprayed incautiously. It is reasonable to expect that any such exposure would be transient, especially amongst users in professional settings such as care homes or veterinary establishments.

Exposure of pets to the product could be expected to be dermal and, to some extent, oral by licking treated surfaces. Exposure could be either to the liquid or dried product present on treated surfaces.

Review of the available information for each of the ingredients did not indicate any toxicological cause for concern, in terms of hazard and risk, to either human users or consumers or to animals that may come into contact with the products. Likewise, there was no suggestion of adverse environmental effects that might be due to use of this product in the indicated applications.

In addition, the biodegradability of the product has been considered. Of the ingredients listed in the formulation the only one of potential concern was sorbitan monooleate, ethoxylated, otherwise known as Tween 80 or polysorbate 80 (CAS 9005-65-6). Reference to the Hazardous Substances Data Bank indicated that, under aerobic conditions, Polysorbate 80, present at 1,000 mg/L, was 17.8% degraded over 20 days, with most activity occurring in the first 5 or 6 days of operation, when incubated in a bioreactor containing soil (92.8% sand; 4.0% silt; 0.6% clay; 0.4% organic carbon content) from a historically contaminated field site from a southern Maryland wood treatment plant



(quoting Kim SH, Weber WJ Jr; Environ Toxicol Chem 24: 268-276 (2005)). This suggests a half life of degradation of about 56 days. This source was less clear in terms of anaerobic degradation indicating that Polysorbate 80, present at 200 mg/L, exhibited 16.6 and 18.6% methane production in glucose and lactate-fed cultures, respectively, after 7 days using enrichment cultures developed from organochlorine-contaminated estuarine sediment and incubated at 22 °C under methanogenic conditions (quoting Yeh DH et al; Water Sci Technol 38: 55-62 (1998)). Overall, it is considered that this chemical would be biodegradable with time.

In terms of REACH legislation, this substance would not be classified as persistent as its half-life in soil is less than 120 days (Annex XIII of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (December 2006.)

Other ingredients in the formulation were either citrate metal salts, hydrogen peroxide or a simple organic compound that would be readily biodegraded. The percentages of these ingredients did not indicate any cause for toxicological concern.

This review considered the potential addition to the product of one of three fragrances at 1%. Although there may be some requirement for labelling the product to indicate its content of allergens, there was no toxicological concern. All suggested fragrances were accompanied by information indicating that their use in this product type is acceptable at the percentage indicated.

A skin irritation test was conducted *in vitro* using the Epiderm™ model of human skin for both the 50% dilution and undiluted products; neither was considered to be irritant.

It is understood that the product may be sprayed near food or food products, but without the presence of fragrances (which might lead to tainting of the food). Polysorbate 80 is a food additive and a pharmaceutical excipient and, as such, is not considered to pose any undue toxicological hazard or risk in this application.

In the light of the review of these ingredients individually and of the product as a whole, it is considered that there is no need for further toxicity testing beyond the dermal cytotoxicity test already being conducted.

Conclusion

It is concluded that the intended use of this product is not expected to be associated with undue adverse effects on human users/consumers or on pets or the environment. It is also concluded that the product would be biodegradable.

Signed:..... Date:.....

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