



INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY

WORLD HEALTH ORGANIZATION

**TOXICOLOGICAL EVALUATION OF SOME
FOOD COLOURS, ENZYMES, FLAVOUR
ENHANCERS, THICKENING AGENTS, AND
CERTAIN FOOD ADDITIVES**

WHO FOOD ADDITIVES SERIES 6

The evaluations contained in this publication were prepared by the Joint FAO/WHO Expert Committee on Food Additives which met in Rome, 4-13 June 1974¹

World Health Organization Geneva 1975

¹ Eighteenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. techn. Rep. Ser., 1974, No. 557. FAO Nutrition Meetings Report Series, 1974, No. 54.

MICROBIAL GLUCOSE OXIDASE* (*Aspergillus niger*)

Explanation

This enzyme preparation has been evaluated for acceptable daily intake by the Joint FAO/WHO Expert Committee on Food Additives (see Annex 1, Ref. No. 27) in 1971.

Since the previous evaluation additional data have become available and are summarized and discussed in the following monograph. The previously published monograph has been expanded and is reproduced in its entirety below.

BIOLOGICAL DATA

BIOCHEMICAL ASPECTS

No data available.

TOXICOLOGICAL STUDIES

Acute toxicity

None available.

Short-term studies

Rat

Three groups of 10 male and 10 female Charles River rats were fed 0, 5 and 10% of *Aspergillus niger* mycelial preparation in their diet for 90 days. There were no overt signs of toxicity, and food consumption and growth were not affected. There was a drop in the efficiency of food utilization for all dosed groups, it was significant for the males in the high dose group. The haematological, the clinical and the ophthalmoscopic data revealed no significant differences between the groups. There were significant increases in the relative kidney weight of females in both dosage groups. The gross and microscopic findings were mostly related to chronic respiratory disease and kidney lesions including hydropelvis or hydronephrosis, which did not appear to be treatment-related (Swann & Cox, 1973).

* This enzyme preparation is prepared from some varieties of *Aspergillus niger*.

Duckling

Groups of five ducklings received in their diet either 0, 1, 5 or 10% of enzyme for 29 days. Growth, feed efficiency, behaviour and survival were similar in all groups except the 10% level which showed some growth retardation. No gross liver lesions or differences in mean liver weight were noted. Histopathology was normal. No toxic element was noted (FDRL., 1963).

Long-term studies

None available.

Comments:

Aspergillus niger is a common contaminant of food. The available information indicates that it is not pathogenic to man. A duckling study was done and a 90-day study in rats is now available showing no toxicological effects at 10% in the diet. This meets the requirements as laid down by the Committee.

EVALUATION

Acceptable daily intake not specified.*

REFERENCES

- FDRL (1963) Unpublished report No. 84600d of the Food and Drug Research Laboratories submitted by Miles Chemical Co.
- Swann, H. E. & Cox, G. E. (1973) Unpublished report 1a. No. 1223 submitted by Searle Biochemicals

* The statement "ADI not specified" means that, on the basis of the available data (toxicological, biochemical, and other), the total daily intake of the substance, arising from its use or uses at the levels necessary to achieve the desired effect and from its acceptable background in food, does not, in the opinion of the Committee, represent a hazard to health. For this reason, and for the reasons stated in individual evaluations, the establishment of an acceptable daily intake (ADI) in mg per kg of body weight is not deemed necessary.

See Also:

[Toxicological Abbreviations](#)