

Flavocide® acute neurotoxicity study underway (OECD 424)

Highlights

- An acute neurotoxicity study is underway to generate essential safety data for inclusion in the Flavocide® regulatory dossier
- Study to assess whether Flavocide has any effect on the neurological health of rats
- The dose range-finding study arm has been completed and the preliminary report for the main study is scheduled to be received in May 2026
- This is one of the key studies required to be included in regulatory submissions and support subsequent commercialisation of Flavocide

Melbourne, Australia: Bio-Gene Technology Limited (ASX:BGT or ‘Bio-Gene’ or ‘the Company’), an Australian company developing the next generation of novel insecticides derived from nature, is pleased to announce that the acute Flavocide neurotoxicity study is underway. This study is required to support international submissions for regulatory approval and is designed to assess whether Flavocide, a Bio-Gene insecticidal active ingredient, has any effect on the neurological health of rats (**OECD 424 Study**).

The results will inform key aspects of Bio-Gene’s dossier of mammalian toxicology data to be submitted to the Australian Pesticides & Veterinary Medicines Authority (**APVMA**) in Australia, in support of its application for the registration of Flavocide as an active constituent.

Summary of the OECD 424 Study

This OECD 424 Study is designed to evaluate any potential neurotoxicity effects in adult rats following oral exposure to Flavocide, including the evaluation of any changes in neuro-behaviour and neuropathology.

This study is being conducted by a Contract Research Organisation (**CRO**) in accordance with OECD guidelines and Good Laboratory Practice (**GLP**).

Key study parameters:

Study name:	OECD 424: Acute Neurotoxicity Study of Flavesone in Rats
Study objectives:	To identify any effects on the nervous system from exposure to Flavocide; contribute to characterisation of any alterations; determine dose-response relationships to support No Observed Adverse Effect Level (NOAEL) dose estimation and safety guidelines.
Test material:	Flavocide technical material (≥96% flavesone)
Animal type(s):	Norway rat (<i>Rattus norvegicus</i>), Wistar strain, both sexes

Protocol summary:	This is a GLP-compliant OECD Test Guideline 424 acute oral study (including initial dose range-finding arm) to select dose levels followed by evaluation of general health, motor activity, neuro-behaviour and neuropathology.
Study endpoints:	Mortality and general health (including regular clinical observations); neuro-behavioural effects using a standard Functional Observational Battery (FOB) and motor activity assessments at key time points after dosing; body weight and food consumption over the observation period; pathology assessment, including necropsy and microscopic evaluation of nervous system tissues (with histopathology focused on the control and high-dose groups, and extended if required)
Reporting & key dates:	<p>The non-GLP dose range-finding arm of the OECD 424 Study (DRF Study) to identify the appropriate dose of Flavocide to be administered to the animals in the main study has been completed.</p> <p>The in-life phase of the main OECD 424 study (Main Study) is expected to finish during April 2026, with the preliminary report scheduled to be received in May 2026 and final report during June 2026.</p>

Relevance of the OECD 424 Study

The OECD 424 Study is an internationally recognised toxicology study used globally¹ to evaluate potential neurotoxicity effects of a test substance (i.e. Flavocide) in rats. The study will establish a robust toxicological profile critical for human health risk assessments and labelling of Flavocide products.

The data generated will be suitable for submission to regulatory bodies operating under the OECD's Mutual Acceptance of Data arrangements (**OECD MAD Framework**), including OECD member countries such as Australia, New Zealand, USA, Canada, Japan, the United Kingdom and many European countries. The data will also be accepted in non-member countries that are full adherents to the **OECD MAD Framework**, including South Africa, Singapore, India, Brazil, Argentina, Malaysia and Thailand.

The OECD 424 Study is a core study required to be included in the application for registration of Flavocide active constituent to be filed with the **APVMA**. The study will generate data to

¹ The protocol used for this study complies with the OECD Test Guideline No. 424 'Neurotoxicity Study in Rodents' (1997). This guideline forms part of the OECD's Mutual Acceptance of Data (MAD) system, which provide guidelines for the testing of chemicals using a collection of the most relevant internationally agreed testing methods used by governments, industry and independent laboratories. These guidelines provide a common basis for co-operation between regulatory bodies across the 38 OECD member countries (and a further seven non-member countries) to assess the toxicity of new chemical substances.

define neurotoxicity potential, safe exposure limits, and guidance for product use, while providing insights for evaluating safety for people and animals.

This OECD 424 Study will provide information that can:

- identify whether the nervous system is permanently or reversibly affected by oral exposure to Flavocide;
- contribute to the characterisation of any nervous system alterations associated with exposure to Flavocide and to understand the underlying mechanism; and
- determine dose and time-response relationships to estimate the **NOAEL**, which can be used to establish safety criteria for Flavocide.

Tim Grogan, Managing Director & Chief Executive Officer for Bio-Gene said:

“The rigorous regulatory requirements governing the development and approval of new insecticides, such as Flavocide, require data to be generated to show that they are safe to animals and do not adversely affect neurological development. The results of this neurotoxicity study will form a key part of Bio-Gene’s regulatory dossier and also provide important insights to ensure the safe use of Flavocide.”

“Now that the dose range-finding study arm has been completed, we are looking forward to receiving the preliminary report of the Main Study, which is scheduled for May 2026.”

Relationship to Other Studies

The OECD 424 Study is one of the more complex toxicity studies required to be included in the Flavocide regulatory dossier. It is in addition to the shorter-term mammalian toxicology studies already completed and complements other ongoing and planned long-term toxicity studies, such as the *OECD 443: Extended One Generation Reproductive Toxicity Study (Rat)*, which is also currently underway (see ASX announcement on 9 February 2026).

Flavocide Background and Study Context

Flavocide is a novel insecticide that is identical to flavesone, a naturally occurring plant compound present in some eucalypts. Bio-Gene has developed a proprietary process to synthesise this molecule and produce it in commercial quantities. Bio-Gene owns all intellectual property created by its contractors relating to the synthesis of Flavocide.

Flavocide exhibits a new mode of action – that is, the way it controls or knocks down an insect – and is able to overcome insect resistance. Bio-Gene is developing Flavocide to address the global problem of insecticide resistance in public health, crop protection, grain storage and consumer applications.

The Company’s business model involves entering into licensing arrangements with commercial partners internationally to formulate and develop insecticidal products that contain Flavocide. Bio-Gene will then be entitled to receive up-front and milestone payments and then royalties from its commercial partners upon sale of these new products. Bio-Gene’s

business model also includes the supply of Flavocide to these partners in commercial quantities under a commercial supply agreement.

Approved for release on ASX by Bio-Gene Board of Directors.

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About Bio-Gene Technology Limited

Bio-Gene is an Australian company developing novel bio-insecticides to address the global challenges of insecticide resistance. Its unique products are based on a naturally occurring class of compounds proven to overcome insecticide resistance to control pests with minimal impact on human health and the environment.

Bio-Gene's products have multiple applications across crop protection, grain storage, public health and consumer uses. They provide new options derived from nature to meet market demand for effective and safe pest management solutions.

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About this announcement

This announcement has been prepared in accordance with the *AusBiotech Code of Best Practice for Reporting by Life Sciences Companies* (2nd Edition), 2013. The objectives of this Code are to:

- a. provide a reference tool to guide public Australian life science companies in effective and informative communication to the market according to a guidance framework;
 - b. incorporate international best practice in reporting, and thus maintain and enhance the reputation, integrity and credibility of the Australian life science sector; and
 - c. provide information to investors about the disclosure framework that identifies the key drivers of value for life science companies, supporting more informed investment decisions.
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