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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 15670.11-2017

Replacing GB/T 15670-1995

Toxicological test methods for pesticides registration - Part 11:Short-term repeated dose 28-day dermal toxicity study

农药登记毒理学试验方法 第11部分：短期重复经皮染毒(28天)毒性试验

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Foreword

GB/T 15670 "Pesticide registration toxicology test method" is divided into the following parts. - Part 1. General; - Part 2. Acute oral toxicity test; - Part 3. Sequential method of acute oral toxicity test; - Part 4. Acute oral toxicity test probability unit method; - Part 5. Acute percutaneous toxicity test; - Part 6. Acute inhalation toxicity test; - Part 7. Skin irritation/corrosivity test; - Part 8. Acute eye irritation/corrosivity test; - Part 9. Skin allergy (sensitization) test; - Part 10. Short-term repeated oral exposure (28 days) toxicity test; - Part 11. Short term repeated percutaneous exposure (28 days) toxicity test; - Part 12. Short-term repeated inhalation exposure (28 days) toxicity test; - Part 13. Subchronic toxicity test; - Part 14. Bacterial response mutations; - Part 15. Micronucleus test of mammalian bone marrow polychromatic erythrocytes; - Part 16. Chromosome aberration test of mammalian bone marrow cells in vivo; - Part 17. Chromosome aberration of spermatogonia/spermatocytes in mammals; - Part 18. Sexual lethal test of rodents; - Part 19. In vitro mammalian cell chromosome aberration test; - Part 20. In vitro mammalian cell gene mutation test; Part 21. Systemic DNA synthesis (UDS) test for mammalian hepatocytes in vivo; - Part 22. DNA damage and repair/programmed DNA synthesis in mammalian cells in vitro; - Part 23. Teratogenic tests; - Part 24. Two generations of reproductive toxicity tests; - Part 25. Acute delayed neurotoxicity test; - Part 26. Chronic toxicity test; - Part 27. Cancer test; - Part 28. Chronic toxicity and carcinogenesis trials; - Part 29. Metabolic and toxic kinetic tests. This part is part 11 of GB/T 15670. This part is drafted in accordance with the rules given in GB/T 1.1-2009. This part of the part of GB/T 15670-1995 "pesticide registration toxicology test method". This section is the same as the subacute percutaneous toxicity test part of GB/T 15670-1995.

--- modify and adjust the overall structure and layout format; - Added "normative reference documents" (see Chapter 2); - Added "terms and definitions" (see Chapter 3); - an increase of the "test summary" (see Chapter 5);

--- "test pesticide" as "the test substance", the disposal of solid subject, the sample dilution, preparation made specific requirements (see 6.1, 1995 edition 9.2); - the dose setting and grouping, made a more explicit request, put forward if necessary, additional high dose

exposure group and additional control group To understand the persistence, reversibility or late toxic effects of toxic effects (see 6.3,

--- "test step" instead of the original "method of administration" "time of administration", in order to ensure the test results can be compounded, with particular emphasis on the concept Observe the concentration, concentration, capacity, exposure area and exposure density of the test substance, and the microclimate that pollutes the environment, such as Temperature, humidity and wind speed (see 6.4,.1995, 9.5);

--- Added "test results and evaluation" (see Chapter 7);

--- Added "Test Report" (see Chapter 8). This part of the People's Republic of China Ministry of Agriculture made and centralized. This part of the drafting unit. Ministry of Agriculture Pesticide Testing Institute. This part of the main drafters. Zhang Baoxiang, Zhang Liying, Tao Chuanjiang. This part of the previous version of the standard to replace the release of the situation.

--- GB/T 15670-1995. Pesticide registration toxicology test method Part 11. Short-term repeated percutaneous exposure (28 days) Toxicity test

1 Scope

GB/T 15670.11-2017 is the Chinese national standard on toxicological test methods for pesticides registration - part 11:short-term repeated dose 28-day dermal toxicity study, in the field of agriculture. The /T suffix marks it as a recommended standard: it is not compulsory by itself, but it becomes binding as soon as a contract, a tender or a customer specification calls it up - which in practice is how most foreign buyers meet it. It was issued on 12 July 2017 by the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China; Standardization Administration of China, and has been in force since 1 February 2018. Classification: ICS 65.100, CCS B17. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This part of GB/T 15670 specifies the basic principles, methods and requirements for short-term repeated transdermal exposure (28 days) toxicity test. This section applies to the short-term repeated transdermal exposure (28 days) toxicity test for pesticide registration.

2 Normative reference documents

The following documents are indispensable for the application of this document. For dated references, only the dated edition applies to this article Pieces. For undated references, the latest edition (including all modifications) applies to this document. Laboratory Animal Environment and Facilities

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Short-term repetitive percutaneous exposure to toxic short-termrepeateddosedermaltoxicity Repetitive skin damage caused by repeated exposure to 10% of life of experimental animals.

3.2 No adverse effects on dose levels observed Noobservedadverseeffectlevel; NOAEL Under the prescribed test conditions, the test substance of the harmful effect associated with the exposure was not observed by the existing technical means and the detection index High dose or concentration.

3.3 Observed at the lowest dose level of harmful effects lowestobservedadverseeffectlevel; LOAEL Under the prescribed test conditions, the lowest dose of the test substance, which is detrimental to the exposure, was observed using the prior art and the assay Amount or concentration.

3.4 Target organ A substance that causes a significant toxic effect in the body.

4 Purpose of the test

Through the short-term repeated percutaneous exposure (28 days) toxicity test, provided in the specified test period, the skin after repeated exposure to the subject caused by Health hazard data, a preliminary understanding of the transdermal permeability of the test substance, toxicity characteristics, the role of target organ, from the dose - effect and dose - response relationship (NOAEL) was observed without observing the level of adverse effects (LOAEL), and also observed the lowest dose level (LOAEL) Which can provide the basis for the selection of dose and observation index of subchronic and chronic percutaneous toxicity test.