# Data Evaluation Report on the Acute Toxicity of Lambda-Cyhalothrin to Fish (*Leuciscus idus*)

EPA MRID Number 44584001

**Data Requirement:**

| | |
|---|---|
| EPA DP Barcode | 369007 |
| EPA MRID | 44584001 |
| EPA Guideline | OPPTS 850.1075 |

**Test material:** Lambda-Cyhalothrin **Purity:** 87.7% (1:1 ratio of two isomers)
Common name: Lambda-Cyhalothrin
Chemical name: IUPAC: (*R*)-α-cyano-3-phenoxybenzyl (1*S*)-*cis*-3-(Z-2-chloro-3,3,3-trifluoroprop-1enyl)-2,2-dimethylcyclopropanecarboxylate
(*S*)-α-cyano-3-phenoxybenzyl (1*S*)-*cis*-3-(Z-2-chloro-3,3,3-trifluoroprop-1enyl)-2,2-dimethylcyclopropanecarboxylate
CAS name: [1α(*S**),3α(Z)]-(±)-cyano(3-phenoxyphenyl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxlate
CAS No.: 91465-08-6
Synonyms: None Provided

**Primary Reviewer:** John Marton **Signature:**
**Staff Scientist, Cambridge Environmental, Inc.** **Date:** 09/08/09

**Secondary Reviewer:** Teri S. Myers **Signature:**
**Senior Scientist, Cambridge Environmental, Inc.** **Date:** 09/09/09

**Primary Reviewer:** Amanda Solliday **Date:** 09/18/09
**Biologist, EPA/OPP/EFED**

**EPA PC Code** 128897

**Date Evaluation Completed:** 09/18/09

**CITATION:** Kent, S.J. and T. Shillabeer. 1997. LAMBDA-CYHALOTHRIN: Acute toxicity to golden orfe (*Leuciscs idus*). Unpublished study performed by Brixham Environnmental Laboratory, Devon, UK. Laboratory report number BL6142/B. Study sponsored by Zeneca Ag Products, Wilmington, Delaware. Study completed December 1997.


**EXECUTIVE SUMMARY:**

In a 96-h acute toxicity study, golden orfe (*Leuciscus idus*) were exposed to lambda-cyhalothrin at nominal concentrations of 0 (negative and solvent controls), 0.030, 0.060, 0.12, 0.24, 0.48, and 0.96 µg ai/L under flow through conditions. The 96-hour mean-measured concentrations were <0.0020 (<LOQ; controls), 0.017, 0.026, 0.056, 0.11, 0.28, and 0.48 µg ai/L. The reviewer-calculated TWA concentrations were <0.0020 (<LOQ; controls), 0.017, 0.026, 0.055, 0.11, 0.27, and 0.47 µg ai/L. The 96-h $LC_{50}$ (determined using TWA concentrations) was 0.078 µg ai/L. The $EC_{50}$ value could not be determined as sub-lethal data were only summarized for an entire treatment level (no count information provided). The NOAEC value was 0.055 µg ai/L based on mortality and sublethal effects. Sub-lethal effects (quiescent, sounding, erratic swimming, spiraling, loss of balance, rapid respiration, labored respiration, ceased swimming, light discoloration, surfacing, irregular respiration, gulping air) were observed in the groups exposed to TWA concentrations of 0.11, 0.27 and 0.47 µg ai/L of lambda-cyhalothrin. Based on the results of this study, lambda-cyhalothrin would be classified as very-highly toxic to *Leuciscus idus* in accordance with the classification system of the U.S. EPA.

This study is scientifically sound. Because the golden orfe (*Leuciscus idus*) is not a recommended test species, this acute freshwater fish toxicity study is considered supplemental.

**Results Synopsis**

Test Organism Size/Age: mean weight- 2.15g (range 1.46-4.01g); mean length 53 mm (47-66mm). Size determined from negative control fish at test termination.

Test Type: flow-through

$LC_{50}$: 0.078 µg ai/L 95% C.I.: 0.055-0.11 µg ai/L
NOAEC: 0.055 µg ai/L Probit Slope: N/A
$EC_{50}$: Not Determined

Endpoints calculated using TWA concentrations.
Endpoint(s) Affected: mortality and sub-lethal effects including quiescence, sounding, erratic swimming, spiraling, loss of balance, rapid respiration, labored respiration, ceased swimming, light discoloration, surfacing, irregular respiration and gulping air.

## I. MATERIALS AND METHODS

**GUIDELINE FOLLOWED:** This study was conducted following guidelines outlined in U.S. EPA (1985), Hazard Evaluation Division, Standard Evaluation Procedure EPA-540/9-85-006, Acute Toxicity Test for Freshwater Fish. The following deviations from OPPTS 850.1075 were noted:

1. Golden orfe (*Leuciscus idus*) is not a recommended test species.
2. DO concentrations (mg/L) were reported; however, the % saturation was not specified.
3. The photoperiod was not reported.
4. There was only one replicate per treatment. At least two replicates are preferred to perform statistical analysis.
5. The reported biomass loading rate (0.96 g/L) exceeded the recommended maximum loading rate for flow-through tests (0.5 g/L).
6. Results from a periodic screening analysis of the dilution water were not reported.

These deviations impact the acceptability of the study.

**COMPLIANCE:** Signed and dated No Data Confidentiality, GLP, and Quality Assurance statements were provided. This study was conducted in compliance with the UK principles of Good Laboratory Practice (UK GLP Regulations 1997). These principles are in accordance with the OECD Principles of Good Laboratory Practice 1981 (OECD Environment Monograph No. 45).

**A. MATERIALS:**

**1. Test material** Lambda-Cyhalothrin

**Description:** dark-brown solid

**Lot No./Batch No. :** Not reported

| | |
|---|---|
| **Purity:** | 87.7%; the test material is a racemic mixture (1:1 ratio) containing the R and S isomers |
| **Stability of compound under test conditions:** | Samples collected at test initiation yielded recoveries of 47-83% of nominal. Recoveries from samples collected at 48 and 96 hours yielded recoveries of 58-94 and 55-89% of 0-hr measurements, respectively. The nominal 0.48 µg ai/L treatment level (the second highest dose) yielded the lowest recoveries at 48 and 96 hours (58 and 55% of 0 hr, respectively); all other recoveries at 48 and 96 hrs were ≥70% of 0 hr. The reviewer-calculated TWA concentrations yielded recoveries of 43-57% of nominal. |
| **Storage conditions of test chemicals:** | Stored in the dark at ambient temperature |

**Physicochemical properties of Lambda-Cyhalothrin.**

| Parameter | Values | Comments |
|---|---|---|
| **Water solubility at 20EC** | 5 µg ai/L | |
| **Vapor pressure** | Not Reported | |
| **UV absorption** | Not Reported | |
| **pKa** | Not Reported | |
| **Kow** | Not Reported | |

**2. Test organism:**

**Species:** Golden Orfe (*Leuciscus idus*)
*EPA recommends a cold water species (preferably rainbow trout Oncorhynchus mykiss) and a warm water species (preferably bluegill sunfish Lepomis macrochirus).*

**Age at test initiation:** Not Reported
**Weight at study initiation:** mean 2.15 g (range 1.46-4.01 g); based on negative control fish at test termination
*EPA recommends: mean 0.5 - 5 g.*
**Length at study initiation:** mean 53 mm (range 47-66 mm); based on control fish at test termination
**Source:** London Aquatic Company Ltd., Greenwood Nurseries, Theobalds Park Road, Enfield, Middlesex, UK

**B. STUDY DESIGN:**

**1. Experimental Conditions**

a. Range-finding study: A range-finding study was not reported.

b. Definitive Study

**Table 1: Experimental Parameters**

| Parameter | Details | Remarks<br>*Criteria* |
|---|---|---|
| Acclimation | | |
| Period: | 17 days | *The recommended acclimation period is a minimum of 14 days. No feeding should occur within 48 hours of the test. Pretest mortality should be <5% during acclimation period.* |
| Conditions: (same as test or not) | Same as test | |
| Feeding: | Fish were fed daily with Keystart® (a proprietary product). Feeding was terminated 72-hrs prior to testing. | |
| Health: (any mortality observed) | No disease or mortalities reported | |

| Parameter | Details | Remarks<br>*Criteria* |
|---|---|---|
| Duration of the test | 96 hours | *The recommended test duration is 96 hours.* |
| Test condition<br><br>Static/flow-through<br><br>Type of dilution system - for flow-through method.<br><br><br><br><br><br><br><br>Renewal rate for static renewal | <br><br>Flow-through<br><br>Dynamic flow-through system. Test material was fed to mixing chambers by a peristaltic pump and the dilution water was supplied using a capillary flow control system. Magnetic stirrers in the mixing chambers were used to ensure mixing before the test solutions passed to the exposure vessels. The test solutions were renewed at a nominal rate of 250 mL/min to produce 8 volume additions per 24 hours.<br><br>N/A | <br><br>*Static renewal is one method to ensure relatively continuous concentrations when the test material is not stable under test conditions. The renewal cycle should be shorter than the time it takes for the concentration of the test material to decline to <70 percent.*<br><br>*A reproducible supply of toxicant is recommended. Consistent flow rate is usually 5-10 vol/24 hours; meter systems should be calibrated before and after study and checked twice daily during test period.* |
| Aeration, if any | None provided | *Aeration is not recommended. If aeration is necessary, test solutions must be analyzed periodically to verify exposure.* |

| Parameter | Details | Remarks<br>*Criteria* |
|---|---|---|
| Test vessel<br><br>Material: (glass/stainless steel)<br><br>Size:<br><br>Fill volume: | <br><br>Borosilicate glass<br><br>54 L<br><br>45 L | <br><br>*Materials should be chosen to minimize sorption of test chemicals, such as glass, stainless steel or perfluorocarbon plastic. Test vessels must be of adequate size to maintain a biomass loading rate of <0.5 g FWF/L for flow-through tests.*<br><br>*Test vessel size is usually 19 L (5 gal) or 30 x 60 x 30 cm.*<br>*Fill volume is usually 15-30 L of solution.* |
| Source of dilution water<br>Quality: | Dechlorinated tap water supplied from a 100$m^3$ reservoir with an average retention time of 24 hrs. Water was passed through activated carbon, coarsely filtered to remove particulate material and dechlorinated with sodium thiosulfate. Water was then held in a different reservoir and then passed through a UV sterilizer and a second set of filters of 25 and 10 µm and then to a third storage tank. Water was delivered through a ring circuit to a temperature controlled header tank in the laboratory set to a nominal temperature of 12°C and finally filtered to 5 µm before use. | *Recommended source of dilution water is soft, reconstituted water or water from a natural source. Dilution water should be intensely aerated before the study. EPA does not recommend the use of dechlorinated tap water. However, its use may be supportable if the biological responses for the organisms and chemical analyses of residual chlorine meet conditions in the Agency 850.1075 guidelines for dilution water.* |

| Parameter | Details | Remarks<br>*Criteria* |
|---|---|---|
| Water parameters:<br>Hardness | 43.3-46.3 mg/L as $CaCO_3$ | Conductivity- 212-218µS/cm<br>Alkalinity- 25.0 mg/L as CaCO3<br>$NH_3$-N- 0.02 mg/L |
| pH | 7.01-7.39 | *Hardness:*<br>*EPA recommends 40 - 180 mg/L as $CaCO_3$* |
| Dissolved oxygen | 9.2-10.4 mg/L | |
| Total Organic carbon | Not Reported | *pH:*<br>*EPA recommends 6.0 – 8.0.* |
| Particulate Matter | Not Reported | *Dissolved Oxygen:*<br>*EPA recommends:*<br>*Static: ∃ 60% during first 48 hrs and ∃ 40% during second 48 hrs*<br>*Flow-through: ∃ 60%* |
| Metals | Not Reported | |
| Pesticides | Not Reported | |
| Chlorine | <4 µg/L | *Temperature:*<br>*Recommended temperature is 12.0°C for coldwater species and 17.0 – 25.0 °C for warmwater species.* |
| Temperature | 12.0-12.3°C | |
| {Salinity for marine or estuarine species} | N/A | *Chlorine*<br>*Maximum concentration = 0.003 mg/L* |
| Intervals of water quality measurement | Temperature, DO, and pH were measured at 0, 24, 48, 72, and 96 hours. Temperature was also continuously monitored in the negative control. | *Salinity:*<br>*EPA recommends 30-34‰ (parts per thousand) for marine, 10-17‰ for estuarine fish, weekly range < 6‰.*<br><br>*Water quality should be measured at beginning of test and every 48 hours.* |
| Number of replicates/groups:<br>control:<br>solvent control:<br>Treatment: | <br>1<br>1<br>1/level | *Recommended number of replicates includes a control and five treatment levels. Each concentration should be 60% of the next highest concentration; concentrations should be in a geometric series.* |
| Number of organisms per replicate /groups:<br>control:<br>solvent control:<br>Treatment: | <br>20<br>20<br>20 | *Number of organisms per replicate should be ∃ 10/concentration.* |

| Parameter | Details | Remarks<br>*Criteria* |
|---|---|---|
| Biomass loading rate | 0.96 g/L | *Biomass loading rate should be <0.8 g FWF/L for flow through tests.* |
| Test concentrations:<br>nominal:<br><br>measured:<br><br>TWA (reviewer-calculated): | 0 (negative and solvent controls), 0.030, 0.060, 0.12, 0.24, 0.48, and 0.96 µg ai/L<br><br><0.0020 (<LOQ; controls), 0.017, 0.026, 0.056, 0.11, 0.28, and 0.48 µg ai/L<br><br><0.0020 (<LOQ; controls), 0.017, 0.026, 0.055, 0.11, 0.27, and 0.47 µg ai/L | |
| Solvent (type, percentage, if used) | DMF (0.1 mL/L) | *The solvent should not exceed 0.5 ml/L for static tests or 0.1 ml/L for flow-through tests.* |
| Lighting | Artificial lighting, photoperiod not reported | *The recommended photo period is 16 hours of light and 8 hours of dark with a 15-30 minute transition period.* |
| Feeding | Fish were not fed during the definitive exposure. | *Fish should not feed during the study.* |
| Recovery of chemical<br>Frequency of determination<br>Level of quantization<br>Level of detection | <br>0, 48, and 96 hours<br>0.0020 µg ai/L<br>Not Reported | |
| Positive control {if used, indicate the chemical and concentrations} | N/A; a positive control was not used | |
| Other parameters, if any | None reported | |

**2. Observations:**

**Table 2: Observations**

| Parameter | Details | Remarks<br>*Criteria* |
|---|---|---|
| Parameters measured including the sublethal effects/toxicity symptoms | -mortality<br>-sub-lethal effects | |
| Observation intervals | 0, 24, 48, 72, and 96 hours | |
| | | *Observation intervals should be a minimum of every 24 hours.* |
| Were raw data included? | Raw mortality data were provided, but only a summary of sub-lethal effects data were included. | |
| Other observations, if any | None | |

## II. RESULTS AND DISCUSSION:

### A. MORTALITY:

After 96 hours of exposure, mortality was 0% in the controls and mean-measured 0.017-0.056 µg ai/L treatment groups and 100% in the 0.11-0.48 µg ai/L treatment groups. Complete mortality was observed in the two highest treatment groups after 24 hours and in the 0.11 µg ai/L treatment group after 48 hours. The study authors reported that at 24 hours, 17 of the remaining fish at the two highest treatment levels were deteriorating and were therefore sacrificed to prevent unnecessary suffering. The remaining fish at the 0.11 µg ai/L treatment level at 48 hours were also sacrificed to avoid unnecessary suffering. The study authors reported NOAEC and $LC_{50}$ values of 0.056 and 0.078 µg ai/L, respectively.

**Table 3: Effect of Lambda-Cyhalothrin on Mortality of *Leuciscus idus*.**

| Mean-Measured and (Nominal) Concentrations µg ai/L | No. of Fish at Start of Study | Observation Period | | | | | |
|---|---|---|---|---|---|---|---|
| | | 24 Hrs | | 48 Hrs | | 96 Hrs | |
| | | No Dead | % mortality | No Dead | % mortality | No Dead | % mortality |
| Negative Control | 20 | 0 | 0 | 0 | 0 | 0 | 0 |
| Solvent Control | 20 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0.017 (0.030) | 20 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0.026 (0.060) | 20 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0.056 (0.12) | 20 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0.11 (0.24) | 20 | 0 | 0 | 20 | 100 | 20 | 100 |
| 0.28 (0.48) | 20 | 20 | 100 | 20 | 100 | 20 | 100 |
| 0.48 (0.96) | 20 | 20 | 100 | 20 | 100 | 20 | 100 |
| NOAEC | 0.056 µg ai/L | | | | | | |
| $LC_{50}$ | 0.078 (0.056-0.11) µg ai/L | | | | | | |
| Positive control, if used mortality: $LC_{50}$: | N/A | N/A | N/A | N/A | N/A | N/A | N/A |

**B. NON-LETHAL TOXICITY ENDPOINTS:**

Sub-lethal effects were noted in mean-measured 0.28 and 0.48 µg ai/L treatment groups at 24 hours with >30% of the fish exhibiting effects and were ultimately sacrificed to prevent unnecessary suffering as their condition was deteriorating. Toxicity symptoms included quiescence, sounding, erratic swimming, spiraling, loss of balance, rapid respiration, labored respiration, ceased swimming and discoloration. By 48 hours, >30% of the fish in the mean-measured 0.11 µg ai/L treatment group were exhibiting similar effects (erratic swimming, spiraling, loss of balance, rapid respiration, labored respiration, ceased swimming, surfacing, irregular respiration and gulping air) and were sacrificed as fish in the two highest treatment levels were. No effects were noted in the controls or mean-measured 0.017-0.056 µg ai/L treatment groups.

**Table 4: Sub-lethal Effect of Lambda Cyhalothrin on *Leuciscus idus*.**

| Mean-Measured and (Nominal) Concentrations µg ai/L | Observation Period | | |
|---|---|---|---|
| | 24 Hrs | 48 Hrs | 96 Hrs |
| | % Affected | % Affected | % Affected |
| Negative Control | A.N. | A.N. | A.N. |
| Solvent Control | A.N. | A.N. | A.N. |
| 0.017 (0.030) | A.N. | A.N. | A.N. |
| 0.026 (0.060) | A.N. | A.N. | A.N. |
| 0.056 (0.12) | A.N. | A.N. | A.N. |
| 0.11 (0.24) | <10%[a] | >30%[cdefghjkl] | -- |
| 0.28 (0.48) | >30%[abcdefg] | >30%[b] | -- |
| 0.48 (0.96) | >30%[abcdefghi] | 30%[b] | -- |
| NOAEC | 0.056 µg ai/L | | |
| LOAEC | 0.11 µg ai/L | | |
| $EC_{50}$ | Not Reported | | |
| Positive control, if used % sublethal effect: $EC_{50}$: | N/A | N/A | N/A |

a= quiescent, b= sounding, c= erratic swimming, d= spiraling, e= loss of balance, f= rapid respiration, g= labored respiration, h= ceased swimming, i= light discoloration, j= surfacing, k= irregular respiration, l= gulping air
A.N.- all surviving fish appear normal and healthy

**C. REPORTED STATISTICS:**

The $LC_{50}$ value and the 95% confidence intervals were calculated by the Brixham Environmental Laboratory computer program "LC50" using Stephan's method. Analyses were conducted using the mean-measured concentrations.

**D. VERIFICATION OF STATISTICAL RESULTS:**

Statistical Method: The 96-hr $LC_{50}$ value (and 95% C.I.) was determined using the binomial probability method via Toxanal statistical software. The NOAEC value was visually determined based on the lack of mortality and sub-lethal effects in the controls and TWA 0.017-0.055 µg ai/L treatment groups and complete mortality in the TWA 0.11-0.47 µg ai/L treatment groups. All toxicity values are based on the reviewer-calculated TWA concentrations.

$LC_{50}$: 0.078 µg ai/L 95% C.I.: 0.055-0.11 µg ai/L
NOAEC: 0.055 µg ai/L
Probit Slope: N/A 95% C.I.: N/A

**E. STUDY DEFICIENCIES:**

See Guideline Deviation section above. In addition, there were no treatment levels with partial kills.

**F. REVIEWER'S COMMENTS:**

The reviewer's results were similar to those of the study authors, with the exception that the reviewer's results were based on the TWA concentrations while the study authors reported toxicity values based on the mean-measured concentrations. Therefore, the reviewer's results are reported in the Executive Summary and Conclusions section of this DER.

The reviewer calculated the TWA concentrations using the following equation:

$$C_{TWA} = \frac{\left(\frac{C_1 + C_0}{2}\right)(t_1 - t_0) + \left(\frac{C_2 + C_1}{2}\right)(t_2 - t_1) + \left(\frac{C_{n-1} + C_2}{2}\right)(t_{n-1} - t_2) + \left(\frac{C_n + C_{n-1}}{2}\right)(t_n - t_{n-1})}{t_n}$$

where:
C TWA is the time-weighted average concentration,
C j is the concentration measured at time interval j (j = 0, 1, 2,...n)
t j is the number of hours (or days or weeks, units used just need to be consistent in the equation) of the test at time interval j
(e.g., t 0 = 0 hours (test initiation), t 1 =24 hours, t 2 =96 hours)

An initial definitive test was conducted. However, this test was terminated due to high mortality in the lowest treatment level.

The dissolved oxygen concentrations were reported, but not expressed as percent saturation. The percent saturation appears to be greater than 60 percent, however (the lower bound according to guideline recommendations).

The in-life portion of the definitive toxicity test was conducted from September 29 to October 3, 1997.

**G. CONCLUSIONS:**

This study is scientifically sound. Because the golden orfe (*Leuciscus idus*) is not a recommended test species, this study is considered supplemental. The 96-hr NOAEC and $LC_{50}$ values were 0.055 and 0.078 µg ai/L, respectively.

$LC_{50}$: 0.078 µg ai/L 95% C.I.: 0.055-0.11 µg ai/L
NOAEC: 0.055 µg ai/L Probit Slope: N/A
$EC_{50}$: Not Determined

Endpoints based on TWA concentrations.
Endpoint(s) Affected: mortality and sub-lethal effects including quiescence, sounding, erratic swimming, spiraling, loss of balance, rapid respiration, labored respiration, ceased swimming, light discoloration, surfacing, irregular respiration and gulping air.

## III. REFERENCES:

U.S. Environmental Protection Agency. 1985. Hazard Evaluation Division. Standard Evaluation Procedure EPA-540/9-85-006. Acute Toxicity Test for Freshwater Fish.

OECD. 1992. OECD Guidelines for Testing of Chemicals. Method 203. Fish, Acute Toxicity Test.

EEC Directive 92/69/EEC. 1992. Methods for the determination of ecotoxicity. C2, Acute toxicity for Fish. L383A.

Stephan, C.E. 1977. Methods for calculating an LC50 In: Aquatic Toxicology and Hazard Evaluation. Mayer F.L., Hamelink, J.L., Editors. Proceedings 1st Annual Symposium on Aquatic Toxicology. ASTM, 1977, STP 634 65-84.

## APPENDIX I. OUTPUT OF REVIEWER'S STATISTICAL VERIFICATION:

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| CONC. | NUMBER EXPOSED | NUMBER DEAD | PERCENT DEAD | BINOMIAL PROB. (PERCENT) |
|---|---|---|---|---|
| .47 | 20 | 20 | 100 | 9.536742E-05 |
| .27 | 20 | 20 | 100 | 9.536742E-05 |
| .11 | 20 | 20 | 100 | 9.536742E-05 |
| .055 | 20 | 0 | 0 | 9.536742E-05 |
| .026 | 20 | 0 | 0 | 9.536742E-05 |
| .017 | 20 | 0 | 0 | 9.536742E-05 |

THE BINOMIAL TEST SHOWS THAT .055 AND .11 CAN BE
USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT
CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL
ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 7.778175E-02

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE
PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE
NOR THE PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.

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