



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EFGWB: 91-017
Chemical Barcode: 118401
DP Barcode: D157949
Case: 2585

JAN - 4 1991

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: Review of Phase IV Package for Hydramethylnon (AMDRO)

FROM: James A. Hetrick, Ph.D., Chemist *James A. Hetrick*
Environmental Chemistry Review Section #1
EFGWB/EFED

THRU: *for* Robert W. Holst, Ph.D., Deputy Branch Chief *Henry Jacoby*
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

Paul J. Mastradone, Ph.D., Section Chief *Paul J. Mastradone*
Environmental Chemistry Review Section #1
EFGWB/EFED

TO: Amy Rispin, Ph.D., Branch Chief
Science Analysis & Coordination Branch
Environmental Fate and Effects Division (H7507C)

The Phase IV review package for List B chemical hydramethylnon (case no. 2585) was received by EFGWB on 19 November 1990.

EFGWB has reviewed the use pattern information as provided by the LUIS report dated 6 November 1990 for hydramethylnon (AMDRO). Based on information from the LUIS report and EFGWB files, Amdro is used as an insecticide to control imported fire ants, harvester ants, big-headed ants, and cockroaches.

The LUIS report indicates the following uses: i) terrestrial food & feed crop; ii) terrestrial non-food crop; iii) terrestrial non-food & outdoor; iv) indoor residential; v) indoor non-food; and vi) indoor medical. Amdro can be applied to the following crops: terrestrial food & feed crops, i.e., agricultural crops, pastures, and rangeland; ornamental and shade trees; ornamental herbaceous plants; and ornamental lawns and turf. The maximum application rate for Amdro, formulated as a bait with 0.88 to 1.65% a.i., is 0.033 lbs a.i. A⁻¹.

In the Phase III reponse, the registrant [American Cyanamid Company] agreed to submit new environmental fate studies for the following data requirements:

- (160-5) Chemical Identity
- (161-1) Hydrolysis
- (161-2) Photodegradation in Water
- (161-3) Photodegradation on Soil

- (162-1) Aerobic Soil Metabolism
- (162-2) Anaerobic Soil Metabolism
- (163-1) Leaching and Adsorption/Desorption
- (164-1) Terrestrial Field Dissipation
- (201-1) Droplet Spectrum
- (202-1) Drift Field Evaluation.

Additionally, the registrant submitted study summaries for a product chemistry study (MRID 106033), confined crop rotational study (MRID 00061706), and fish bioaccumulation studies (MRID 101611). These studies were reviewed as part of the Phase IV package.

The attached table outlines the status of the data requirements for terrestrial food & feed crop, terrestrial non-food crop, terrestrial non-food & outdoor, indoor residential, indoor non-food, and indoor medical. At this time, the following data requirements have not been satisfied:

- 160-5 Chemical Identity
- 161-1 Hydrolysis
- 161-2 Photodegradation in Water
- 161-3 Photodegradation on Soil
- 162-1 Aerobic Soil Metabolism
- 162-2 Anaerobic Soil Metabolism
- 163-1 Leaching and Adsorption/Desorption
- 164-1 Terrestrial Field Dissipation
- 201-1 Droplet Spectrum
- 202-1 Drift Field Evaluation

cc Hank Jacoby

PHASE IV ENVIRONMENTAL FATE SUMMARY TABLE FOR HYDRAMETHYLINON (Case # 2585)

Chemical Code : 118401
 Pesticide Type : Insecticide

Reviewer: J. Hetrick
 Date: 12/17/90

Uses (LUIS 11-06-90): Terrestrial Food & Feed Crop, Terrestrial Non-Food Crop, Terrestrial Non-Food Outdoor, Outdoor Residential, Indoor Non-Food, Indoor Medical, Indoor Residential

Submitted Studies/ Addendums	DER/Addendum Review/Summary Identification	DER/Addendum Review/Summary Review Conclusions	Additional Data/Info Required?
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CHEMICAL/PHYSICAL DATA:

160-5. Chemical Identity 106033 YES^a

DEGRADATION-LAB:

161-1. Hydrolysis None^b YES

Photodegradation:
 161-2. In Water None^b YES

161-3. On Soil None^b YES

161-4. In Air None NA^c

METABOLISM-LAB:

161-1. Aerobic Soil None^b YES

162-2. Anaerobic Soil None^b YES^d

162-3. Anaerob. Aquat. None YES^d

162-4. Aerobic Aquatic None NA

MOBILITY STUDIES:

163-1. Leaching and Adsorp./Desorp. None^b YES

163-2. Volatilit. (Lab) None NA^e

163-3. Volatilit. (Field) None NA^e

PHASE IV ENVIRONMENTAL FATE SUMMARY TABLE (continued)

	Submitted Studies/ Addendums	DER/Addendum Review/Summary Identification	DER/Addendum Review/Summary Review Conclusions	Additional Data/Info Required?
<u>DISSIPATION-FIELD:</u>				
164-1. Terrest. (Soil)	None ^b			YES
164-3. Forestry	None			NA
164-4. Combin./Tank Mix	None			NA
164-5. Long Term Terr.	None			RESERVED ^c
164-5. Long Term Aqua.	None			NA
<u>ACCUMULATION STUDIES:</u>				
165-1. Conf. Rot. Crops	00061706	DER(91-0176)	SATISFIES	NO ^d
165-2. Field Rot. Crops	None			RESERVED
165-3. Irrigated Crops	None			NA
165-4. Fish (Lab)	101611	DER(91-0176)	SATISFIES	NO
165-5. Aqua. Non-target Organ. (Field)	None			RESERVED ^e
<u>SPRAY DRIFT:</u>				
201-1. Droplet Spect.	None			YES ^f
202-1. Field Spray Drift Evaluation	None			YES ^f
<u>GROUNDWATER MONITORING:</u>				
166-1. Small Propect.	None			RESERVED ^g
166-2. Small Retrop.	None			RESERVED ^g
166-3. Large Retrop.	None			RESERVED ^g
<u>SURFACE WATER:</u>				
167-1. Field Runoff	None			RESERVED ^g
167-2. Surface Water Monitoring	None			RESERVED ^g

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KEY:

- 1) Addendum(EFGWB#/Date) - placed in the second column to indicate that a review (having the indicated EFGWB# and date) of the addendum identified by MRID# in the first column/same row is in the file.
- 2) DER(EFGWB#/Date) - placed in the second column to indicate that a data evaluation record for the study identified by MRID# in the first column/same row is in the file attached to a review with the indicated EFGWB# and date.
- 3) DNS/Salv./Supp. - placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not satisfy (DNS) the data requirement, but could possibly be salvageable (Salv.) to do so with the submission of additional information or limited data. The results of the study can be used for supplemental information (Supp.).
- 4) DNS/Salv./NSupp. - placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not satisfy (DNS) the data requirement, but could possibly be salvageable (Salv.) to do so with the submission of additional information or limited data. The results of the study should not be used for supplemental information (NSupp.).
- 5) DNS/NSalv./Supp. - placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not satisfy (DNS) the data requirement, does not appear to be salvageable (NSalv.) to do so with the submission of additional information or limited data. The results of the study can be used for supplemental information (Supp.).
- 6) DNS/NSalv./NSupp. - placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not satisfy (DNS) the data requirement, and does not appear to be salvageable (NSalv.) to do so with the submission of additional information or limited data. The results of the study should not be used for supplemental information (NSupp.).
- 7) DNPS/Salv./Supp. - placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not partially satisfy (DNPS) the data requirement, but could possibly be salvageable (Salv.) to do so with the submission of additional information or limited data. The results of the study can be used for supplemental information (Supp.).
- 8) DNPS/Salv./NSupp. - placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not partially satisfy (DNPS) the data requirement, but could possibly be salvageable (Salv.) to do so with the submission of additional information or limited data. The results of the study should not be used for supplemental information (NSupp.).
- 9) DNPS/NSalv./Supp. - placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not partially satisfy (DNPS) the data requirement and does not appear to be salvageable (NSalv.) to do so with the submission of additional information or limited data. The results of the study can be used for supplemental information (Supp.).

- 10) DNPS/NSalv./NSupp. - placed in the third column to indicate that the study or addendum identified by MRID# in the first column/same row does not partially satisfy (DNPS) the data requirement, and does not appear to be salvageable (NSalv.) to do so with the submission of additional information or limited data. The results of the study should not be used for supplemental information (NSupp.)
- 11) Dropped Uses(codes) - placed in the second column to indicate that there are no DERs or summaries available for the study identified by MRID# in the first column/same row, but that the registrant has indicated in their Phase III response that all uses for which the data requirement is applicable will be dropped. Verify through the LUIS report that the uses have been dropped.
- 12) MRID#/MRID#A - placed in the first column to indicate that the study and addendum (A) whose MRID#s immediately precede and succeed the "/" , respectively, are coupled. If a MRID# was not assigned to the addendum, substitute the date of submission for the MRID# followed by an "A" to indicate that it's an addendum. If neither a MRID# or submission date is available, but the addendum was submitted as part of the Phase III response, substitute "Phase IIIA" for "MRID#A".
- 13) NA - placed in last (4th) column to indicate that the data requirement is not applicable to the uses listed in the LUIS report.
- 14) No - placed in the final (4th) column to indicate that no additional information or data is needed to completely satisfy an applicable data requirement. Identify in a footnote any studies that individually only partially satisfied the data requirement, but combined completely satisfies the data requirement. If the data requirement is not applicable to any of the uses listed in the LUIS report, use the "NA" designation defined above instead of "No".
- 15) No Information - placed in the second column to indicate that no DER or summary is available for the study identified by MRID# in the first column/same row, and that the registrant has not indicated in their Phase III response that they will submit another study or will drop uses to make the data requirement not applicable.
- 16) None - placed in the first column to indicate that the registrant did not list any studies or addendums in their Phase II and/or III responses for the given data requirement. In addition, EFGWB has no record of any studies or study/addendum combinations satisfying or partially satisfying the data requirement.
- 17) Not Reviewable - placed in the third column to indicate that based upon a review of the summary identified by MRID# in the second column/same row, EFGWB concludes that the study identified by MRID# in the first column/same row will not satisfy or partially satisfy the data requirement and appears not to be salvageable to do so. Therefore, the study should not be reviewed.
- 18) Reviewable - placed in the third column to indicate that based upon a review of the summary identified by MRID# in the second column/same row, EFGWB concludes that the study identified by MRID# in the first column/same row may possibly satisfy or partially satisfy the data requirement, or could possibly be salvageable to do so. Therefore, the study should be reviewed.
- 19) Reserved - placed in the final (4th) column to indicate that the data requirement is being held

in reserve. Indicate in a footnote what information is needed to decide whether or not to impose the data requirement.

20) SIR Review - placed in the final (4th) column to indicate that one or more studies is currently in review.

21) Study Withdrawn - placed in the second column to indicate that there are no DERs or summaries available for the study identified by MRID# in the first column/same row, but that the registrant has indicated in their Phase III response that another study will be submitted.

22) Summary (MRID#) - placed in the second column to indicate that a DER is not available for the study identified by MRID# in the first column/same row, but that a study summary with the indicated MRID# was submitted as part of the Phase III response. If a summary is submitted for a study which also has a DER, identify the DER in the second column instead of the summary. (Note that the MRID# of the summary is not the same as the MRID# of the study it summarizes).

23) SWB Submitted - placed in the final (4th) column to indicate that one or more studies will be submitted by the registrant as indicated in their Phase III response.

24) Waived - placed in the final (4th) column to indicate that the data requirement has been waived. Identify the reason for the waiver and the EFGWB#/date of EFGWB's waiver recommendation in a footnote.

25) Yes - placed in the final (4th) column to indicate that additional information and/or data are needed to satisfy the data requirement. Specify in a footnote what additional information and/or data are needed.

FOOTNOTES:

a. The chemical identity data are incomplete for hydramethylnon. The following product chemistry data are required to support an environmental fate profile.

Vapor Pressure (mm Hg)	hydramethylnon
	< 6 X 10 ⁻⁸ (25°C)
	< 2 X 10 ⁻⁸ (35°C)
	< 2 X 10 ⁻⁸ (45°C)
K _{ow} Solubility (mg ml ⁻¹)	Not Determined
Distilled Water	Not Determined

* Vapor pressure data were taken from a product chemistry summary (MRID 106033).

b. Environmental fate studies have been submitted to support the data requirement; however, in the Phase III response, the registrant [American Cyanamid] believes previous studies cannot support the data requirements under current Subdivision N guidelines. Therefore, the registrant will submit new environmental fate studies to support the data requirements.

c. The vapor pressure for hydramethylnon is < 6 X 10⁻⁸ mm Hg (25°C); this vapor pressure is less than the 1 X 10⁻⁶ mm Hg environmental fate trigger. Therefore, the air photodegradation studies are waived for parent hydramethylnon because it is not a volatile compound.

- d. The registrant will submit an anaerobic aquatic metabolism study in lieu of the anaerobic soil metabolism study.
- e. The vapor pressure for hydramethylnon is $< 6 \times 10^{-8}$ mm Hg (25°C); this vapor pressure is less than the 1×10^{-6} mm Hg environmental fate trigger. Therefore, laboratory and field volatility studies are waived for parent hydramethylnon because it is not a volatile compound.
- f. Long-term terrestrial field dissipation studies are reserved pending review of acceptable field dissipation studies.
- g. The confined rotational crop study conditionally satisfies the data requirement. If a label amendment is sought to increase the maximum application rate > 0.066 lbs A⁻¹, to decrease the minimum rotation interval < 90 days, or to use in rotation with leafy food crops, new studies are required under the proposed conditions to confirm residue accumulation.
- h. Accumulation studies for aquatic non-target organisms are reserved pending review of both an acceptable fish accumulation study and product chemistry datum (K_{ow}).
- i. Based on a LUIS Report (6 November 1990), hydramethylnon is aerially applied; therefore, spray drift data are required to support the reregistration. Upon official cancellation of this application method [aerial application] these data will no longer be required.
- j. The data requirements are reserved pending review of acceptable environmental fate studies.

DATA EVALUATION REVIEW

I. Study Type: Confined Rotational Crop Study

II. Citation: Gatterdam, P. E. 1979. AMDRO fire ant insecticide (CL 217300): Uptake and Residues of Radioactivity in Fallow-Crops Grown in Soil Containing Aged Residues of Carbon-14 Labeled CL 217,300. performed and submitted by American Cyanamid Company Princeton, NJ. MRID 00061706.

III. Reviewer:

Name: James A. Hetrick, Ph.D., Chemist
Title: Environmental Chemistry Review Section #1
Organization: EFGWB/EFED/OPP

James A. Hetrick

IV. Approved by:

Name: Paul J. Mastradone, Ph.D., Chief
Title: Environmental Chemistry Review Section #1
Organization: EFGWB/EFED/OPP

Paul J. Mastradone

JAN 7 1991

V. Conclusions:

This study conditionally satisfies the 165-1 data requirement. A conditional acceptance of this study is based on the following use limitations:

1. The maximum application rate of CL 217,300 is ≤ 0.066 lbs A⁻¹.
2. The minimum rotation interval is ≥ 90 days.
3. Restricted use to rotations for root and grain food crops.

Amdro ([¹⁴C]-CL 217,300), applied at rates of 0.066 and 0.013 lbs A⁻¹ and incubated over a 90 day rotation interval, was not accumulated in either edible or non-edible plant tissues. The total concentration of accumulated [¹⁴C]-CL 217,300 residue in mature plant tissues [radish tubers and leaves, snap bean leaves and pods, and barley seeds] was below the analytical detection limit of 1 $\mu\text{g kg}^{-1}$. However, the total concentration of [¹⁴C]-CL 217,300 residue in mature barley leaves ranged from 4 to 9 $\mu\text{g kg}^{-1}$.

The [¹⁴C]-CL 217,300 residues in plant tissues were not identified using a confirmatory analytical method; instead, the residue content was determined by total ¹⁴C. Total residue analysis is not a definitive method because it does not allow for identification of specific [¹⁴C]-CL 217,300 residues. Because the

total concentration of [¹⁴C]-CL 217,300 residues is less than the Subdivision N tolerance of 50 $\mu\text{g kg}^{-1}$, identification of specific residues is not required.

VI. Materials and Methods:

A microplot field study was conducted on a loam soil in Princeton, NJ. Physicochemical properties of the loam soil are shown in Table 1. Each microplot was a confined soil column with an area of 7,779 cm² and a depth of 19.80 cm. Two of the microplots were amended with radiolabeled CL 217,300 to approximate either a 1X application rate at 6 g a.i. A⁻¹ (0.013 lbs A⁻¹) or a 5X application rate at 30 g a.i. A⁻¹ (0.066 lbs A⁻¹). These treatments received a uniform surface application of 72 or 360 [redacted] coated with CL 217,300 (Specific Activity 22.98 μCi mg⁻¹). Additionally, a microplot was not treated with CL 217,300 to serve as an experimental control. Each microplot was then allowed to incubate for 90 days under natural conditions.

After the 90 day fallow rotation interval, the microplots were cultivated to a soil depth of 4.9 cm and seeded with 22 cm wide rows of radish (Cherry Belle), snapbeans (Tender Pod), and barley (Spring Laker). The plants were watered and weeded to maintain good plant growth.

The plants [radish, snapbeans, and barley] were harvested 66 days post planting. For each microplot, the foliage of snapbeans and barley was removed by cutting the stems at the soil surface. The foliage for snapbeans and barley was further separated into foliar material [i.e., leaves, stems, chaff, etc.] and seeds. The radishes were harvested by removing whole plants and separated into leafy and tuber material. The plant material was then washed with water to remove adhering soil particles.

The plant tissue samples (with the exception of barley seedheads) were extracted with methanol-acetone in a Waring blender. Each extract was filtered through a sinter glass filter and then concentrated by evaporation. The [¹⁴C]-residue concentration in plant extracts, extracted plant residues, and barley seedheads was measured by combustion via LSC. The LSC procedure had a level of quantification of 1 μg kg⁻¹.

I. Study Author's Results and/or Conclusions:

A. After a 90 day crop rotation interval, the concentration of [¹⁴C]-CL 217,300 residue in both edible and non-edible plant tissues (exception barley foliage) was below the analytical detection limit of 1 μg kg⁻¹ (Table III).

B. After a 90 day crop rotation interval, barley foliage had accumulated a measurable concentration of [¹⁴C]-CL 217,300 residues (4-9 μg kg⁻¹) (Table III). The accumulation of [¹⁴C]-CL 217,300 residues in barley foliage may be due, in part, to dehydration at maturity.

Reviewer Comments:

A. The [¹⁴C]-CL 217,300 residues in plant tissues were not identified using a confirmatory analytical method such as TLC or HPLC; the residue content was determined by total ¹⁴C. Total residue analysis is not a definitive method because it does not allow for identification of specific [¹⁴C]-CL 217,300 residues. Because the total concentration of [¹⁴C]-CL 217,300 residues is less than the Subdivision N tolerance of 50 μg kg⁻¹, identification of specific residues is not required. In future experiments, the bioaccumulated pesticide residues, if possible, should be quantified and identified using at least two analytical methods.

B. No leafy vegetables [lettuce, etc.] were grown in the confined rotational crop study. Therefore, this study does not support Amdro use in rotation systems for leaf crops. In future experiments, pesticide residues accumulation should be assessed in rotation systems for root, grain, and leaf crops.

Page _____ is not included in this copy.

Pages 12 through 13 are not included.

The material not included contains the following type of information:

- Identity of product inert ingredients.
 - Identity of product impurities.
 - Description of the product manufacturing process.
 - Description of quality control procedures.
 - Identity of the source of product ingredients.
 - Sales or other commercial/financial information.
 - A draft product label.
 - The product confidential statement of formula.
 - Information about a pending registration action.
 - FIFRA registration data.
 - The document is a duplicate of page(s) _____.
 - The document is not responsive to the request.
-

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

DATA EVALUATION REVIEW

I. Study Type: Fish Accumulation Study

II. Citation: Barringer, D. 1982. Identification and Characterization of CL 217,300 and It's Metabolite in Bluegill Sunfish Exposed to 1.8 ppb of CL 217,300 in Water. performed by ABC Laboratory, Columbia MO and American Cyanamid, Princeton NJ. sponsored by American Cyanamid Company, Princeton NJ. Received by EPA 4/4/90. MRID 101611.

III. Reviewer:

Name: Richard V. Moraski, Chemist
Title: Environmental Chemistry Review Section #1
Organization: EFGWB/EFED/OPP

IV. Approved by:

Name: Paul J. Mastradone, Ph.D., Chief *Paul J. Mastradone*
Title: Environmental Chemistry Review Section #1
Organization: EFGWB/EFED/OPP

JAN 7 1991

Compiled by:

Name: James A. Hetrick, Ph.D., Chemist *James A. Hetrick*
Title: Environmental Chemistry Review Section #1
Organization: EFGWB/EFED/OPP

V. Conclusions:

This study marginally fulfills the 165-4 data requirement.

In an earlier study, American Cyanamid reported BCF of 34,900 (whole fish), 11,900 (fillets) and 35,900 (viscera) compared to 1300 (whole fish), 780 (fillet) and 1900 (viscera) found in this study.

These results indicate that there is a rather high potential for Amdro accumulating in fish. This conforms with previously reviewed data such that the water solubility is low ($2 \mu\text{g L}^{-1}$) and the octanol-water partition coefficient is moderate to high. (203 to 212 for octanol concentrations of 0.1 to $1 \mu\text{g ml}^{-1}$ and 3000 to 1700 for starting octanol concentrations of 10 to $1000 \mu\text{g ml}^{-1}$.) Depuration occurs but is gradual.

VI. Materials and Methods:

Bluegill sunfish with an initial mean weight of 2.3 g and initial mean length of 43 mm were used in this study. Aerated well water (Table 1) flowed through the aquaria at a rate of 350 ml/min/aquarium. Following the a 24 hr equilibration period, the test concentration was confirmed by radioanalysis before

introducing the fish. One hundred fish were transferred to the control to the control and test chambers. The fish were exposed to a constant average concentration of $1.8 \mu\text{g L}^{-1}$ (Solubility of Amdro = $2 \mu\text{g L}^{-1}$) for 30 days. A 14 day depuration period followed.

The sampling schedule is shown in Table 6. All measurements of radioactivity were made using a LSC system. A steady state approach was used to evaluate data from the bioaccumulation study. A water-fish two compartment model was used to describe movement of test material in and out of fish. This was used to determine the bioaccumulation factor (BFC), uptake rate constant (K_1), and the depuration rate constant (K_2).

VII. Study Author's Results and/or Conclusions:

Table 2 gives the results of the radioanalysis in whole fish, fillet, and viscera during uptake and depuration. The data seem to indicate that after 10 days, a steady state plateau was reached suggesting no further accumulation was occurring. The 30 day bioaccumulation factors of 1300 for whole fish, 780 for fillet, and 1900 for viscera were determined. By linear regression analysis of tissue concentration during uptake and depuration and the two-compartment model, the uptake rate constant, K_1 , is 0.83 ml/gm/day depuration rate constant, $K_2 = 0.44 \text{ day}^{-1}$, and $\text{BFC} = 1900$ (Table 4).

Depuration data (Table 3) indicate a gradual clearance from bluegill tissue up to day 14. At the end of the depuration period, 48% depuration was found in whole fish, 63% in fillet, and 57% in viscera.

Residues in edible tissue and viscera analyzed by TLC indicated that the parent accounted for 56 to 76% of the total residue. The rest was made up of 15 metabolites, one of which was identified as CL 98,724. No metabolites exceeded 6%.

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Pages 16 through 20 are not included.

The material not included contains the following type of information:

- Identity of product inert ingredients.
 - Identity of product impurities.
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