UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

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SUBJECT: Quantitative Risk Assessment for Acifluorfen
(TACKLE/BLAZER)

I. Summary

This quantitative risk assessment for Acifluorfen completes the memo, Preliminary Risk Assessment for Acifluorfen (Tackle/Blazer) dated Sept. 11, 1984.

Acifluorfen is found to be a probable human carcinogen (EPA classification for weight of evidence B2) with a potency factor $Q_1^* = 5.7 \times 10^{-2}$ (for dose in mg/kg body weight/day) based on liver tumors and/or stomach papillomas in mice. The results given below apply to both Tackle (Rhone-Poulence, Inc.) and Blazer (Rohm and Haas Co.) although they are based primarily on the analysis of the Rohne-Poulence 18-month feeding study (Caswell No. 755) of Tackle dated Dec. 17, 1982) and only incidentally on the Rohm and Haas Blazer feeding study (Caswell No. 818D) dated March 6, 1979. Both products exhibit an elevated proportion of animals with liver adenomas and/or carcinomas and (in the Tackle study) stomach papillomas.

Time adjustment (using Druckery's formula(1)) yields a dietary risk in humans for soybeans and for the TMRC(2) of 1.3×10^{-6} and 1.3×10^{-5} respectively which are based on the Tackle potency factor of $Q_1^* = 5.74 \times 10^{-2}$(3). Details are given in Section III-B.

Worker risks ranged from 1.3×10^{-4} (LADD(4) Risks with 1% dermal absorption and no protective clothes) to 8.5×10^{-7} (LADD Risk with 1% dermal absorption and with protective clothes). Additional details are given in Section III-D.

II. Background

The Blazer study was conducted at dose levels well below the maximum tolerated dose and therefore did not exhibit a strong dose-tumor trend; nor were any other remarkable events noted. The study dosages were 7.5, 45, and 270 ppm mixed into the feed. However the high dose, 270 ppm group. was given a dose of 1.25 ppm for the beginning 16 weeks of the study then 270 ppm for the remainder. The more recent work on Tackle was done with treatment doses of 625, 1250, and 2500 ppm; and a strong dose-trend relationship was reported. Consequently since both Tackle and Blazer have the same active ingredient (Acifluorfen - approx 20% in Tackle and 40% in Blazer) and test animals exhibit the same tumor types, the results of this memo may be used to support regulatory action involving Acifluorfen (Blazer/Tackle).

In the 18-month Tackle feeding study 60 B6C3F1 mice per sex were randomly allocated to control and three dose groups (625, 1250, 2500 ppm). Dosing was initiated Oct. 3, 1980 and the terminal kill was conducted April 5-13, 1982. Rhone-Poulence noted statistically significant effects in male but not female groups. Body weight changes are clearly dose related in both males and females. This seems to reflect reduced food efficiency as only high dose males consumed statistically-significantly more food ($p \leq .01$ using Dunnett's test).

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(1) $(Lo/Le)^3$ There Lo = 2 year mouse lifetime and Le = 1 1/2 year experiment. From Druckery 1967 in Truhart, "Potential Carcinogenic Hazards from Drugs - Evaluation of Risk (pp 60-78) Springer Verlag, Berlin, and EPA - Water Quality Criteria Document FR 45:79313-79379.

(2) TMRC represents the Raw Agricultural Commodities listed in 1983 FRC 180.383 excepting peanut hulls and rice straw.

(3) This factor is the geometric mean of $Q_1^* = 7.0 \times 10^{-2}$ (time adjusted for males) and $Q_1^* = 4.6 \times 10^{-2}$ (time adjusted for females) where the exposure level is expressed in mg/kg/day.

(4) LADD = Lifetime Average Daily Dose based on number of days exposed per yr for a 40 yr work life and a 70 yr life span.

III. Quantitative Analysis

A. Trend Analysis

The number of tumors over the number of animals examined in the Tackle study is displayed in Table 1. Since some animals were examined in only one organ but not the other, the totals row is not always the direct sum of the previous rows. We note also that if only one organ is examined and a tumor is found then that animal is counted as a tumor bearing animal (TBA) whether or not the other organ is examined. The tumor data and the time of death or sacrifice is shown in Appendix - Table 1.

Table 1 - MICE DATA

(#Tumor Bearing Animals)/(#Animals Examined)

TACKLE

	Dose (ppm) 0	625	1250	2500
Female - Liver[a]	1/59	6/59	5/60	24/59
Stomach[b]	0/58	3/60	3/58	6/57
TOTAL[c]	1/58[d]	8/59	8/58	26/58
Male - Liver	9/59	21/60	16/57	40/59
Stomach	0/59	0/59	0/59	4/58
TOTAL	9/58	21/60	16/56	41/58

BLAZER

	Dose (ppm) 0	7.5	45	270[1.25]
Female - Liver	7/80	5/69	4/80	15/66
Male - Liver	19/79	18/69	28/80	27/70

(a) Liver adenomas and carcinomas are counted.
(b) Stomach papillomas only are counted.
(c) Mice with both liver and stomach findings are counted only once.
(d) Some mice were examined only in the liver or stomach but not both. This fact and (3) account for the seeming discripencies in the totals row.

The only evidence of a Tackle related effect on survival was in the males where a significant probability value ($p \leq .01$) was observed in the 0 vs 1250 ppm group (The adjusted Chi-Square-comparison).

A dose-tumor trend analysis using the Peto Prevalence Methods (Peto et. al. IARC Supplement II, 1980) Hazard Model for Survival and the Tarone-Breslow Proportional Hazards Model for Survival (Int. Stat. Rev., Vol. 43, No. 1, 1975, pp 45-58) clearly indicate a strong liver tumor and/or stomach papilloma dose relationship (for acifluorfen) in mice for both sexes (i.e., the relationship is statistically significant at $p \leq .0001$. The results are summarized below.

Comparisons of Control vs Other Groups (One-tail Chi-Sq test)

Dose (ppm)	625	1250	2500
Female	.04	.04	$\leq .0001$
Male	.03	.16 NS	$\leq .0001$

Trend Analysis: Statistically significant at $P \leq .0001$ for either sex by all survival procedures [Unadjusted, Adjusted for equal weight for all deaths, and adjusted allocating higher weight to early deaths].

From these tests one may infer the presence of a strong dose-tumor trend (i.e., tumor incidence increases with increasing dose), and a significant difference between the control and any other group.

B. Low Dose Extrapolation

The data were fit to the Multistage (Global 83) and Weibull models giving consistent results in both cases. Since the data came from an 18-month study, the linear coefficient, Q_1^*, was adjusted using Druckery's formula as follows:

$$Q_1^* \text{ for 24 mos} = (Q_1^* \text{ for 18 mos}) \times (24/18)^3$$

For the Multistage model this gives a Q_1^* of 4.67×10^{-2} for females and 7.06×10^{-2} for males. The geometric mean of these were taken giving a combined potency factor of $Q_1^* = 5.74 \times 10^{-2}$ [where exposure level is expressed in mg/kg/day]. Similar results were obtained from the Weibull model where the combined Q_1^* using Druckery's formula was 5.6×10^{-2}. We also note that one can extrapolate foward in time with the Weibull-Time model giving another estimate of Q_1^* adjusted for 24 months. Although the results of doing this (see Table 2) are consistent with Druckery's formula, this latter extrapolation tends (in my opinion) to reflect a slight overfit. For example consider the various female Q_1^*s from the Weibull:

Time (days)	$Q1^*$
369	7.7×10^{-4}
557	1.8×10^{-7}
728	7.2×10^{-2}
728	4.3×10^{-2} (using Druckery's formula)

The two lifetime (i.e. 24 mo.) Q_1^*s of 7.2×10^{-2} and 4.3×10^{-2} are consistent, and this is in agreement with Brown and Hoel[5]. However the higher 7.2×10^{-2} figure obtained from the Weibull model appears to put too much emphasis on tumors discovered late in the study (see Appendix/Table 1).

Table 2

Q^* From the Multistage and Weibull Models for the 18 mo. Tackle Feeding Study on Mice Based on Liver Tumors and Stomach Papillomas.

Multistage Model

Q_1^* at time	Female	Male
18 mo	1.97×10^{-2}	2.99×10^{-2}
24 mo(a)	4.67×10^{-2}	7.06×10^{-2}

Combined $Q_1^* = (4.67 \times 10^{-2} \times 7.06 \times 10^{-2})^{-5} = 5.74 \times 10^{-2}$

Weibull Model

Q_1^* at time	Female	Male
18 mo	1.83×10^{-2}	3.14×10^{-2}
24 mo	7.15×10^{-2}	4.76×10^{-2}
24 mo(a)	4.33×10^{-2}	7.44×10^{-2}

Combined[3] Q_1^* for 24 mo = $(7.15 \times 10^{-2} \times 4.76 \times 10^{-2})^{1/2} = 5.83 \times 10^{-2}$

(a) Estimated with Druckery's formula

(5) Brown, K.G. and Hoel, D.G. (1983) Modeling Time-to-Tumor Data. Fund. Appl. Toxicol. 3:458-469.

5

C. Estimation of Risk Associated With Diet

The daily intake of acifluorfen has been calculated from the tolerances published in ~~the CFR Title 40, paragraph 180.382~~ deleting only the feed through commodities (i.e., rice straw and peanut hulls), using a 1500 gram diet and the standard food factors. The exposures of interest are 2.3×10^{-5} and 2.2×10^{-4} mg/kg/day for soybeans and the TMRC respectively. Using $Q_1^* = 5.74 \times 10^{-2}$ these exposures give rise to upper 95% confidence bounds estimates on dietary risks of 1.32×10^{-6} and 1.26×10^{-5}. Note that when rounded these give the same results reported in Section I. The raw agricultural commodities tolerances upon which these risks are based are given in the appendix.

D. Estimation of Risk Increment Associated with Application of Acifluorfen

There are no dermal absorption studies available for acifluorfen. However, Dr. Robert Zendzian (attached memo to H. Lacayo of September 13, 1984) estimates that 1% of the dermal exposure to Acifluorfen is actually absorbed into the body. The dermal absorption formulas and the various species conversion factors are also given in the appendix.

We consider risks in four work situations: self-application custom application, aerial-pilot (Pilot) aerial-mixer-loader (Air M/L). These terms as well as the estimated exposures may be found in Richard Moraski's EAB review memo to Richard Mountfort dated 21 July 83. This memo is included in the appendix.

Each work situation is considered under the following two exposure senarios:

1. LADD Risk assuming 1% dermal absorption without protective clothing.

2. LADD Risk assuming 1% dermal absorption with protective clothing.

These senario results are given in the tables 3 and 4. The Lifetime Average Daily Dose Risk is calculated from the formula:

$$\text{LADD Risk} = (\text{Daily Exposure}) \times \left(\frac{\#\text{days exposed}}{365 \text{ day year}}\right) \times \left(\frac{40 \text{ Work Yrs}}{70 \text{ Yrs Lifetime}}\right) \times Q_1^*$$

Table 3 - Assume 1% Dermal Absorption ($Q_1^* = 5.74\text{-}10^{-2}$)

Daily Exposure and Ladd Risk for Worst Case without Protective Clothing

Worker Situation	Arrival rate r	#hrs exposed h	Dermal(†) Absorption	Inhalation	TOT Dose mg/kg/day	Q_1^* x Total	No. days exposed/yr	LADD Risk
Self-Application	.417	4	.041285	.000048	.041333	$2.37\text{x}10^{-3}$	2	$7.4\text{x}10^{-6}$
Custom Application	.417	8	.146669	.000048	.146717	$8.42\text{x}10^{-3}$	10	$1.3\text{x}10^{-4}$
Pilot	.00775	4	.000767	.0011	.001867	$1.07\text{x}10^{-4}$	7.5	$1.3\text{x}10^{-6}$
Air M/L	.417	4	.041285	.000012	.041297	$2.37\text{x}10^{-3}$	7.5	$2.8\text{x}10^{-5}$

(†) Dermal Absorption $= r\left((h+1) - \frac{1}{a}\left(1 - (1-a)^{h+1}\right)\right)$

when $a = .01$ = 1% dermal absorption

Table 4 - Assume 1% Dermal Absorption ($Q_1^* = 5.74 \times 10^{-2}$)

Daily Exposure and Ladd Risk for Worst Case with Protective Clothing

Worker Situation	Effective[1] Arrival rate	#hrs exposed h	Dermal[2] Absorption	Inhalation	TOT Dose mg/kg/day	Q_1^* x TOTAL	No. days exposed/yr	LADD Risk
Self Application	.0834	4	.008257	.000048	.008305	4.8×10^{-4}	2	1.5×10^{-6}
Custom Application	.0834	8	.029333	.000048	.029381	1.7×10^{-3}	10	2.7×10^{-5}
Pilot	.00155	4	.000153	.0011	.001253	7.2×10^{-5}	7.5	8.5×10^{-7}
Air M/L	.0834	4	.008257	.000012	.008269	4.7×10^{-4}	7.5	5.5×10^{-6}

(1) Effective Arrival Rate = .2 x Arrival Rate
(2) Using dermal absorption formula

The risk estimates shown in table 3 indicate that some workers without protective clothing may be at a risk of 1.3×10^{-4} (not including dietary risk). However these estimates are subject to the following sources of error.

As no dermal absorption study was done, the risk assessment utilizes an expert opinion, a 1% dermal absorption rate. Hence in a situation where absorption is substantially higher, a worker's risk (without protective clothing and excluding dietary risk) could be of the order of 10^{-3} (see Appendix Table 2 for 100% Absorption Rates). On the other hand, since the Tackle study ran for 18 months, it was necessary to estimate full life time exposure using Druckery's formula. These sources of possible error could result in either over or under estimates of the potency Q_1^*.

REMARKS ON BLAZER

The initial review of the Blazer data did not indicate a strong dose-tumor relationship (see Table 1). For example the Peto test gives a border line level of statistical significance, P = .08, for male mice while the female data appears relatively "clean". However it is important to note that during the initial 16 weeks the 270 ppm group was actually given a diet of 1.25 ppm so that the group did not receive a meaningful chemical challenge during their juvenile stage. But one can now assume that a true dose-tumor relationship exists based on the higher dose findings for Tackle and interpolate Blazer rates between those for Tackle and Control. Then, if we model the Blazer data by the multistage model (as was done with Tackle) the following potencies are generated.

$Q_1^* = 7.8 \times 10^{-2}$ (female mice)

$Q_1^* = 1.3 \times 10^{-1}$ (male mice)

These estimates of aciflurofen potency are higher than the corresponding Tackle values. Due to the design (low dose) and conduct of the Blazer study (i.e., the change in dosing by which the low dose group became the high dose group at week 17) we believe that the acifluorfen risk assessment should be based on the Tackle data.

APPENDIX

Contents

Calculation and Conversion Formulas

A. Druckery's Formula

$(Lo/Le)^3$ where Lo = Average animal lifetime
Le = Length of experiment

So, if Q_1^* is estimated from experimental data of Le months using animals with a life span of Lo month and we assume Q_1^* is strictly increasing with time then Druckery's approximation for the Q_1^* value at Lo months would be:

$$Q_1^* \text{ (for Lo mo.)} = (Lo/Le)^3 \times Q_1^* \text{ (for Le mo.)}$$

B. LADD Formula

The lifetime average daily dose (mg/kg/day is approximated by:

LADD = (Dose acquired in one working day in mg/kg/day)

x (No. of working days per year with the chemical)/365

x (40 years of working)/(70 years lifetime)

$$= \text{(One day exposure)} \times \left(\frac{\text{days exposed/yr}}{365}\right) \times \left(\frac{40}{70}\right)$$

C. Conversion of ppm to mg/kg/day

1 ppm in mouse diet = .150 mg/kg/day

Quick Conversion (for ppm only)

$$\text{1 ppm in diet for animal} = \frac{\text{(Wt of diet in grams)}}{\text{(Wt of animal in grams)}}$$

= mg/kg/day for animal

D. Interspecies Conversion Factor

~~Let SA = Surface Area~~

W_h = body weight of human
W_a = body weight of animal
d_h = dose for human (mg/kg/day)
d_a = dose for animal (mg/kg/day)

If we assume the surface area is proportional to $W^{2/3}$ and that equivalent doses (in mg/day) are proportional to surface areas, then $d_h = d_a \times (W_a/W_h)^{1/3}$

For example extrapolation of mouse to an "equivalent" human dose can be done as follows:

1. Convert mouse dose which is usually in ppm to mg/kg/day by

   .15 x (mouse dose in ppm) = mouse dose in mg/kg/day

2. Therefore
   Human Eqiv. Dose = (mouse dose in mg/kg/day)$x(25/60000)^{1/3}$

E. Dermal Absorption Formula

Total Agent Absorbed = A (h, r, a)

$= r \left[(h + 1) - (1/a) \left(1 - (1-a)^{h+1} \right) \right]$

when r = Arrival rate of agent in grams per hour
h = Total number of hours exposed
a = Absorption rate per hour of the amount of agent present

This is the formula used in the calculations and it assumes a "relatively" short absorption time. But the corresponding equation based on the associated differential equation would be:

$$A(h, r, a) = r \left[h + \frac{1}{a} e^{-ah} - \frac{1}{a} \right]$$

12

Commodity	Parts per million
Milk	0.05
Mint hay (peppermint and spearmint)	0.1
Pears	.05
Pistachios	0.05
Poultry, fat	0.05
Poultry, mbyp	0.05
Poultry, meat	0.05
Sheep, fat	0.05
Sheep, mbyp	0.05
Sheep, meat	0.05
Soybeans	0.05
Stone fruits [apricots, nectarines, peaches, plums, (fresh prunes)]	0.05
Walnuts	0.05

(Sec. 408(e) 68 Stat. 514, (21 U.S.C. 346a(e)))

[45 FR 85022, Dec. 24, 1980, as amended at 46 FR 23239, Apr. 24, 1981; 47 FR 1381, 1382, Jan. 13, 1982]

§ 180.382 Triforine; tolerances for residues.

Tolerances are established for residues of the fungicide triforine (*N,N*-[1,4-piperazinediylbis(2,2,2-trichloroethylidene)]bis[formamide]) in or on the following raw agricultural commodities:

Commodity	Parts per million
Apples	0.01
Apricots	8.0
Bell peppers	5.0
Blueberries	.1
Cantaloupes	1.0
Cherries	3.0
Cranberries	.1
Cucumbers	.5
Eggplant	1.0
Nectarines	8.0
Peaches	8.0
Plums	3.0
Prunes (fresh)	3.0
Strawberries	2.0
Watermelon	1.0

(Sec. 408(d)(2), 68 Stat. 512, (21 U.S.C. 346a(d)(2))

[46 FR 15126, Mar. 3, 1981, as amended at 47 FR 18130, Apr. 28, 1982]

§ 180.383 Sodium salt of acifluorfen; tolerances for residues.

Tolerances are established for combined residues of the herbicide sodium salt of acifluorfen (sodium 5-[2-chloro-4-trifluoromethyl)phenoxy]-2-nitrobenzoic acid) and its metabolites (the corresponding acid, methyl ester, and amino analogues) in or on the following raw agricultural commodities;

Commodity	Parts per million
Cattle, kidney	0.02
Cattle, liver	0.02
Eggs	0.02
Goats, kidney	0.02
Goats, liver	0.02
Hogs, kidney	0.02
Hogs, liver	0.02
Horses, kidney	0.02
Horses, liver	0.02
Milk	0.02
Peanuts	0.1
Peanut, hulls	0.1
Poultry, fat	0.02
Poultry, mbyp	0.02
Poultry, meat	0.02
Rice grain	0.1
Rice straw	0.1
Sheep, kidney	0.02
Sheep, liver	0.02
Soybeans	0.1

(Sec. 408(e), 68 Stat. 514 (21 U.S.C. 346(a)(e)); sec. 408(d)(2), 68 Stat. 512 (21 U.S.C. 346a(d)(2)))

[45 FR 24877, Apr. 11, 1980, as amended at 46 FR 61272, Dec. 16, 1981; 47 FR 39490, Sept. 8, 1982]

§ 180.384 N,N-Dimethylpiperidinium chloride; tolerances for residues.

Tolerances are established for residues of the plant growth regulator *N,N*-dimethylpiperidinium chloride in or on the following raw agricultural commodities:

Commodity	Parts per million
Cotton forage	3
Cottonseed	2
Eggs	0.05
Cattle, fat	0.1
Cattle, mbyp	0.1
Cattle, meat	0.1
Goats, fat	0.1
Goats, mbyp	0.1
Goats, meat	0.1
Hogs, fat	0.1
Hogs, mbyp	0.1
Hogs, meat	0.1
Horses, fat	0.1
Horses, mbyp	0.1
Horses, meat	0.1
Milk	0.05
Poultry, fat	0.1
Poultry, mbyp	0.1
Poultry, meat	0.1
Sheep, fat	0.1
Sheep, mbyp	0.1
Sheep, meat	0.1

[45 FR 27937, Apr. 25, 1980]

§ 180.385 Diclofop-methyl; tolerances for residues.

Tolerances are established for the combined residues of the herbicide diclofop-methyl (methyl 2-[4-(2,4-dichlorophenoxy)phenoxy]propanoate) and its metabolites, 2-[4-(2,4-dichlorophenoxy)phenoxy]propanoic acid and 2-[4-(2,4-dichloro-5-hydroxyphenoxy)phenoxy]propanoic acid, in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain	0.1
Barley, straw	0.1
Soybean seed	0.1
Wheat, grain	0.1
Wheat, straw	0.1

(Sec. 408(e), 68 Stat. 514, (21 U.S.C. 346a(e))

[45 FR 23425, Apr. 7, 1980]

§ 180.386 Mefluidide; tolerances for residues.

A tolerance is established for residues of the herbicide mefluidide (*N*-[2,4-dimethyl-5-[[(trifluoromethyl) sulfonyl]amino]phenyl]acetamide) derived from application of the diethanolamine or potassium salts and calculated as the free acid in or on the following raw agricultural commodity:

Commodities	Parts per million
Soybeans	0.01

(Sec. 408(d)(2), 68 Stat. 512 (21 U.S.C. 346a(d)(2)))

[47 FR 13527, Mar. 31, 1982]

§ 180.387 1-methyl 2-[[ethoxy-[(1-methylethyl) amino] phosphinothioyl)oxy)benezoate.

Tolerances are established for combined residues of the insecticide 1-methylethyl 2((ethoxy((1-methylethyl)amino)phosphinothioyl)oxy)benzoate and its cholinesterase inhibiting benzoate metabolites 1-methylethyl 2-((ethoxy ((1-methylethyl)amino)phosphinoyl)oxy)benzoate, 1-methylethy ((ethoxy(1-amino)phospinoyl)oxy)benzoate and methylethyl 2-((ethoxy(amino)phosphinothioyl)oxy)benzoate in or on the following raw agricultura commodities:

Commodity	Parts pe million
Corn, forage and fodder	1
Corn, fresh including sweet, (K+CWHR)	0
Corn, grain	0
Eggs	0 (
Meat, fat, and meat byproducts of cattle, goats, hogs, horses, sheep and poultry	0
Milk	0 (

[45 FR 47147, July 14, 1980]

§§ 180.388—180.389 [Reserved]

§ 180.390 Tebuthiuron; tolerances for res dues.

Tolerances are established for res dues of the herbicide tebuthiuron (*N*-[5-1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]-*N,N'*-dimethylurea) and its meta bolites containing the dimethylethy thiadiazole moiety in or on the follow ing raw agricultural commodities:

Commodity	Parts pe million
Cattle, fat	
Cattle, mbyp	
Cattle, meat	
Goats, fat	
Goats, mbyp	
Goats, meat	
Grass, rangeland, forage	2
Horses, fat	
Horses, mbyp	
Horses, meat	
Sheep, fat	
Sheep, mbyp	
Sheep, meat	

[44 FR 75639, Dec. 21, 1979; 45 FR 17147 Mar. 18, 1980]

§ 180.395 Tetrahydro-5,5-dimethyl-2(1H)-pyrimidinone(3-(4-trifluoromethyl)phenyl)-1-(2-(4-(trifluoromethyl)phenyl)ethenyl)-2-propenylidene)hydrazone; tolerance for residues.

Tolerances are established for resi dues of the insecticide tetrahydro-5,5 dimethyl-2(1*H*)-pyrimidinone(3-(4-(trifluoromethyl)phenyl)-1-(2-(4-