2-14-91

Case No.:2605
Chemical No(s).:114402

CBRS TRANSMITTAL SHEET FOR PHASE 4 REVIEWS

Transmitted to HED on 12/21/90
Case name: Sodium Acifluorfen
Chemical name(s): 5-[(2-chloro-4-trifluoromethyl)-phenoxy]-2-nitrobenzoic acid, Sodium salt
Data submitter(s): BASF Corp.

CRM:Tom Luminello, Jr. Phone #:308-8075

Issues/flags:

This action contains requests for
DATA WAIVER (X)
TIME EXTENSION (X)
ALTERED/DELETED USE ( )

Other: (1) Use information taken from the LUIS report of 11-13-90, Lists A & B DCI labels (264-468; 239-2509-AA; 7969-76), Crop Protection labels (7969-76-264; 7969-79), and Registration Division labels (7969-77; 7969-79). (2) CBRS recommends against any time extensions. The registrant indicated in the Phase 2 submission that adequate studies and the supporting data exist; the time required to transfer these studies from a former registrant should be minimal. (3) Rhone-Poulenc AG Co. is exiting the sodium acifluorfen market.

Branch: CBRS, Phase 4 Review Team
Reviewed by: Stephen R. Funk Date:02/14/91

Approvals:

Section Head: Andrew Rathman Date: 2/14/91

Branch Chief: Edward Zager Date: 2/14/91

cc: Part B Reregistration File, RF, Circ., S. Funk, C. Furlow (PIB, FOD), Betsy Grim (EFED).

Response, by Guideline

Guideline #: 171-4(a) Description: Nature of residue - plants
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: N
Data Waiver( ) Time Extension(X) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): N
Discussion:
The registrant indicated in the Phase 2 response that the requirement would be met with a previously submitted report and that the supporting data did exist. The registrant now requests continued registration until the transfer of documentation from a former registrant is completed. CBRS contends that no additional time should be needed.
MRID: 41688504 (Summary).
The submitted summary covers three soybean studies. CF_3-ring ^{14}C-labeled acifluorfen was applied topically to greenhouse soybean leaflets. No translocation was found in 28 days. The parent and 7 unidentified metabolites were detected (TLC). CF_3-ring (or NO_2-ring ??) ^{14}C-labeled acifluorfen was applied to field-grown soybean plants at a rate of 0.19 lb. a.i./A. Forage total radioactivity declined from 32 ppm to < 0.05 ppm over an 8 week period. Twelve week straw, pods, and grain contained < 0.050 ppm, < 0.030 ppm, and < 0.020 ppm radioactive residues, respectively. No extensive extractions were performed; no residues were characterized. In a third study, CF_3-ring ^{14}C-labeled acifluorfen was applied to field-grown soybean plants at a rate of 0.5 lb. a.i./A. A chloroform soybean forage extract contained parent and 5-[(2-chloro-4-trifluoromethyl)phenoxy]-2-aminobenzoic acid, the sum of both totaling less than 20% of the TRR. Soybean seed was not analyzed. Additional extractions, including methanolic hydrochloric acid, were performed on the forage, but no radiolabeled residues were identified. At least 90% of the radiolabel should be extracted from forage, seed, and straw, and all major metabolites must be identified. Application rates greater than the label rate of 0.75 lb. a.i./A may be required to achieve adequate residue levels for extensive characterization.

Data gap:
The registrant must provide new plant metabolism studies. Sodium acifluorfen radiolabeled in a non-labile part of the molecule (such as one or preferably both of the phenyl rings) should be applied to a legume vegetable (soybeans), a cereal grain (rice), and peanuts reflecting the currently registered uses. The specific activity and/or application rates should be high enough to allow for adequate identification of the metabolites/degradates. Efforts should be made to extract the majority of the radiolabeled chemicals (≥ 90%) and all major radiolabeled extracted metabolites must be characterized. Major components (≥ 0.1 ppm) of unextractable residue should be released (acid, base, enzyme) and identified. The plant material

from the metabolism studies should be tested using the data collection method(s) and enforcement analytical method(s).

Guideline #: 171-4(b) Description: Nature of residue - animals
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: N/A
Data Waiver(X) Time Extension(X) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): N
Discussion:
The registrant indicated in the Phase 2 response that the requirement would be met with a previously submitted report and that the supporting data did exist. The registrant now requests continued registration until the transfer of documentation from a former registrant is completed. CBRS contends that no additional time should be needed. BASF Corp. also requests a data waiver, maintaining that nature of the residue in animals is not needed. The registrant notes that crop field studies have shown sodium acifluorfen levels $\leq$ 0.01 ppm. Other studies have shown very low total radioactive residue levels in milk, eggs, and tissue from the feeding of radiolabeled sodium acifluorfen at levels as high as 10 ppm. Therefore, animal exposure is so low as to be of no concern. CBRS counters that the purpose of 171-4(b) is to determine the nature of the residue, that is, the metabolic path of sodium acifluorfen when fed to livestock. The magnitude (amount) of metabolites is not the issue.

Data gap:
The registrant must provide livestock (poultry, ruminants) metabolism studies. Sodium acifluorfen radiolabeled in a non-labile part of the molecule such as one or preferably both of the aromatic rings should be fed to the livestock for a minimum of three days. Orally treated test animals must be sacrificed within 24 hours of the final dose. The dose administered and the specific activity should be high enough to allow for adequate identification of the metabolites/ degradates. The tissues from the metabolism study should be tested using the data collection method(s) and enforcement analytical method(s).

Guideline #: 171-4(c) Description: Res. analyt. method - plant
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: Y
Data Waiver( ) Time Extension(X) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): N
Discussion:
The registrant indicated in the Phase 2 response that the requirement would be met with a previously submitted report and that the supporting data did exist. The registrant now requests continued registration until the transfer of documentation from a former registrant is completed. CBRS contends that no additional time should be needed. MRID: 92168048; Summary 92168036.

The method is adequate for both data collection and enforcement applications. Sodium acifluorfen and the regulated metabolites are extracted. Sodium acifluorfen, the free acid, and the amine analog metabolite are methylated with diazomethane. The amine is converted to an amide with heptafluorobutyric anhydride. Analysis is by GC with EC detection. Adequate recovery was demonstrated on soybeans, peanuts, beets, carrots, corn, lettuce, sorghum, and wheat. Recovery of the amine is consistently low (ca. 50% - 60%). The method is in PAM Vol. II, Method II; a confirmatory method (A) is also given. The registrant notes that methylating agents other than diazomethane were tried, but the results were unsatisfactory. Recovery of sodium acifluorfen, the free acid, the amine, and the methyl ester are unlikely via the Multi-Residue Protocols.
Additional methods may be needed if new regulated metabolites are found in the new plant metabolism studies.

Data gap:
None, but additional regulatory and data collection methods will be needed if new regulated metabolites are found in the new plant metabolism studies. Any regulatory methods submitted will require an independent method validation as described in PR Notice 88-5 (July 15, 1988). Any new regulated metabolites must be tested through multi-residue Protocol(s) B, C, D, and E. If method validations of the multi-residue methods are found to be necessary, representative (including the most difficult) plant matrices must be tested.

Guideline #: 171-4(d) Description: Res. anal. method - animals
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: Y
Data Waiver( ) Time Extension(X) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): N

Discussion:
MRID: 92168048; Summary 92168036.
The registrant indicated in the Phase 2 response that the requirement would be met with a previously submitted report and that the supporting data did exist. The registrant now requests continued registration until the transfer of documentation from a former registrant is completed. CBRS contends that no additional time should be needed. The method is adequate for both data collection and enforcement applications. Sodium acifluorfen and the regulated metabolites are extracted. Sodium acifluorfen, the free acid, and the amine analog metabolite are methylated with diazomethane. The amine is converted to an amide with heptafluorobutyric anhydride. Analysis is by GC with EC detection. Adequate recovery was demonstrated on beef liver and milk for sodium acifluorfen and the amine analog. The method is in PAM Vol. II, Method II; a confirmatory method (A) is also given. The registrant notes that methylating agents other than diazomethane were tried, but the results were unsatisfactory. Recovery of sodium acifluorfen, the free acid, the amine, and the methyl ester are unlikely via the Multi-Residue Protocols.

Additional methods may be needed if new regulated metabolites are found in the new animal metabolism studies.

Data gap:
None, but additional regulatory and data collection methods will be needed if new regulated metabolites are found in the new animal metabolism studies. Any regulatory methods submitted will require an independent method validation as described in PR Notice 88-5 (July 15, 1988). Any new regulated metabolites must be tested through multi-residue Protocol(s) B, C, D, and E. If method validations of the multi-residue methods are found to be necessary, representative (including the most difficult) animal matrices must be tested.

Guideline #: 171-4(e) Description: Storage stability
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: P
Data Waiver( ) Time Extension(X) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): N
Discussion:
The registrant indicated in the Phase 2 response that the requirement would be met with a previously submitted report and that the supporting data did exist. The registrant now requests continued registration until the transfer of documentation from a former registrant is completed. CBRS contends that no additional time should be needed.
MRID: 92168049, 92168037 Summary.
Storage stability tests were conducted on soybean seeds fortified with radiolabeled sodium acifluorfen (0.1 ppm). Samples were stored for 18 months at -15 deg. C. Analyses were conducted by GC (EC) after storage periods of 0 to 18 months. Recoveries ranged from 25% - 95%. Additional storage stability studies were conducted on sunflower seeds and dry beans (pinto) fortified with the free acid of acifluorfen and the amine analog (0.1 ppm and 0.02 ppm each) and stored for 6 months at -15 deg. C. Recoveries were satisfactory.
Additional storage stability studies are required. Fortification must be with sodium acifluorfen as well as any regulated metabolites. Studies are required for peanuts (nutmeat, hulls, meal, crude oil, refined oil, soapstock), rice (grain, grain dust, polished rice, hulls, bran), processed soybean fractions (meal, hulls, soapstock, crude oil, refined oil), and animal commodities (egg, milk, muscle tissue, liver, cattle kidney).
Data gap:
Storage stability studies must be conducted on all crops and processed products for which a field trial and/or processing study has been (or will be) conducted, as well as representative livestock commodities. Use of field-weathered samples is strongly recommended. Studies are required for peanuts (nutmeat, hulls, meal, crude oil, refined oil, soapstock), rice (grain, grain dust, polished rice, hulls, bran), processed soybean fractions (meal, hulls, soapstock, crude oil, refined oil), and animal commodities (egg, milk, muscle tissue, liver, cattle kidney). Storage conditions must reflect the

storage conditions of the treated samples (from the field trial and processing studies) with respect to temperature, length of storage, containers, lighting, etc. Any metabolites and/or degradates included in the tolerance expressions must be tested as well. The chosen intervals must allow for unforeseen delays in sample storage.

Guideline #: 171-4(f) Description: Mag. res. - potable water
Is requirement applicable? (Y/N): N
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: N/A
Data Waiver(X) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): Y
Discussion:
The registrant stated in the Phase 2 submission that the requirement did not apply. CBRS reserved the requirement pending an examination of the EP labels. The LUIS report and the labels do not indicate any sodium acifluorfen use(s) in/on potable water. The labels do prohibit application to water or wetlands (except as specifically directed for rice) and do advise against accidental contamination of water, as by spray drift or improper waste disposal.

Data gap:
None

Guideline #: 171-4(g) Description: Magnitude residue - fish
Is requirement applicable? (Y/N): N
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: N/A
Data Waiver(X) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): Y
Discussion:
The registrant stated in the Phase 2 submission that the requirement did not apply. CBRS reserved the requirement pending an examination of the EP labels. The LUIS report and the labels indicate no uses in/on bodies of water. Use on rice crops entails possible contamination of fish. The labels (7969-79, 264-468) specifically prohibit the application of sodium acifluorfen to rice fields where crayfish farming is practiced.

Data gap:
None

Guideline #: 171-4(h) Description: Mag. res. - irrigated crop
Is requirement applicable? (Y/N): N
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: N/A
Data Waiver(X) Time Extension( ) Other ( )

Data Waiver/Time Extension (If applicable) Granted? (Y/N): Y
Discussion:
The registrant stated in the Phase 2 submission that the requirement did not apply. CBRS reserved the requirement pending an examination of the EP labels. Neither the LUIS report nor the labels indicate any use that would invoke this requirement, with the possible exception of application of sodium acifluorfen to rice. Chemigation is prohibited for all uses. For rice, irrigation water from rice fields treated with sodium acifluorfen may not be used to apply pesticides to crops not labeled for sodium acifluorfen applications.

Data gap:
None

Guideline #: 171-4(i) Description: Mag. res. - food handling
Is requirement applicable? (Y/N): N
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: N/A
Data Waiver( ) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:

Data gap:
None

Guideline #: 171-4(j) Description: Mag. meat/milk/poultry/eggs
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: N
Data Waiver( ) Time Extension(X) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): N
Discussion:
The registrant indicated in the Phase 2 response that the requirement would be met with a previously submitted report and that the supporting data did exist. The registrant now requests continued registration until the transfer of documentation from a former registrant is completed. CBRS contends that no additional time should be needed.
MRID: 92168050, 92168038 Summary.
A mixture of radiolabeled and nonradiolabeled sodium acifluorfen was fed to four groups of 10 hens each for 56 days. The feed levels were 0, 0.1 (^{14}C-CF_3), 1(^{14}C-CF_3), and 10(^{14}C-COO) ppm, corresponding to 0X, 1.25X, 12.5X, and 125X the anticipated dietary burden. Residues in eggs, tissues, and excreta were analyzed for radioactive content via combustion and LSC. Parent and individual metabolites were not determined; individual components of the tolerance expression must be determined. Radioactivity levels maximized in eggs at 14 days (0.092 ppm), at 44 days (1.126 ppm), and at 24 days (0.816 ppm) for the 0.10, 1.0, and 10 ppm sodium acifluorfen feeding levels, respectively. Samples were stored at -15 deg. C, but actual storage time is unknown. No storage stability data are available.

Radiolabeled sodium acifluorfen (^{14}C-labeled on CF_3 and COO^-) was fed for 21 days to 5 cows. A minimum of 28 days is required. Levels were 0.1 (^{14}C-COO, ^{14}C-CF_3), 1.0 (^{14}C-COO, ^{14}C-CF_3), and 10 (^{14}C-COO) ppm, corresponding to 1.3X, 13.3X, and 133X the anticipated dietary burden. Liquid scintillation counting was used to determine the total radioactivity in milk, tissues, blood, and excreta. Parent and individual metabolites should have been determined. Radioactivity appeared in milk on day 3 for the 1.0 and 10 ppm sodium acifluorfen feeding levels and on day 4 for the 0.1 ppm sodium acifluorfen feeding level. Radioactivity plateaued at 0.003 - 0.004 ppm (day 6) for the 0.1 ppm and 1.0 ppm sodium acifluorfen feeding levels and at 0.029 ppm (day 13) for the 10 ppm sodium acifluorfen feeding level. Storage conditions were described (≤ 3 mos., frozen). A storage stability study is needed.

Data gap:
Sodium acifluorfen must be fed to dairy cattle (ruminant) and poultry. Livestock are to be treated for a minimum of 28 days or longer (until residues plateau in the milk or eggs). Following oral treatment, test animals should be sacrificed within 24 hours of the final dose. Feeding levels should be determined based on the latest crop residue data available or to be generated and should represent the 1X, 3X, and 10X anticipated dietary burden. When determining the feeding levels the registrant should consider the maximum crop residue levels possible and the dietary burden based on Table II Subdivision O - Residue Chemistry Guidelines. Parent and any regulated metabolites are to be determined in milk, eggs, poultry tissue (fat, muscle, liver), and cattle tissue (fat, muscle, liver, kidney). Storage stability studies are needed for both the poultry and ruminant studies.

Sodium Acifluorfen Use Information

Commodity	Max Rate (lbs.a.i./A) Single Appl.	Max Rate (lbs.a.i./A) Seasonal	PHI (days)	Equip-ment[1]
Peanuts[2]	2.0	2.0[3]	75	G, A
Soybeans[2]	0.75	1.0	50	G, A
Rice[2,4]	0.25	0.25	50	A

[1] G = ground; A = aerial. [2] Grazing/forage restriction.
[3] No more than 0.5 lb. a.i./A may be peanut postemergence (after cracking) application. [4] Fish farming restriction; irrigation water (from rice fields) restricted to pesticide applications where sodium acifluorfen use is allowed.

Guideline #: 171-4(k/l) Description: Peanuts field trials/process
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: P
Data Waiver(X) Time Extension(X) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): N
Discussion:
The registrant indicated in the Phase 2 response that the requirement would be met with a previously submitted report and that the supporting data did exist. The registrant now requests continued registration until the transfer of documentation from a former registrant is completed. CBRS contends that no additional time should be needed.
MRID: 92168052, 92168042 Summary.
Field trials were conducted in AL, GA, NC, SC, OK, and FL, an area representing about 76% of domestic peanut production. Application rates generally were at or above the label maximum rates (2.0 lbs. a.i./A per season of which 0.5 lb. a.i./A maximum may be peanut postemergence application). The label PHI is 75 days, and in some cases the field trial PHI's were excessive (Hilton, GA, 97 days; Marianna, FL, 124 days; Little Rock, SC 108 days; Plains, GA 133 days and 144 days; Headland, AL 111 days and 119 days; Calvin, OK 95 days; Shawnee, OK 118 days). Nonetheless, the remaining trials provide minimally adequate data. All applications were by ground equipment. The "Blazer" 2 lbs. a.i./gallon SC/L formulation was used in all trials. In some trials, a spray adjuvant (triton-AG98) was utilized. Hull and nutmeat were analyzed for the parent, the amine analog metabolite, the free acid, and the methyl ester. Samples were stored for no more than 18 months at -15 deg. C. A storage stability study is required. No vines or hay were analyzed, but the labels contain grazing/feeding restrictions.
The registrant requested in the Phase 2 submission a data waiver for the processing study requirement, claiming that the lack of residues of sodium acifluorfen and/or its regulated metabolites in/on peanuts from field trial studies negated the need. To apply this criterion, the field application rate must be greater than the label maximum rate by at least the maximum theoretical processing fraction concentration factor. It can be estimated from established tolerances for other pesticides used on peanuts that the maximum processing concentration factor ranges from 3 to 10. The maximum theoretical concentration factor could be >10 if 100% of the sodium acifluorfen residues concentrate in a fraction that constitutes <10% of the initial peanut weight. Therefore, field trial application rates $\geq$20 lbs. a.i./A, including $\geq$5 lbs. a.i./A applied postemergence, would be required to establish the lack of residue. No such field trials were made. The maximum application rate was 3.3 lbs. a.i./A. The registrant has not presented field trial data to support the waiver request.

Data gap:
The field trial studies are acceptable for review, pending submission of acceptable storage stability studies for peanut hulls and nutmeat. If the new plant metabolism studies reveal new metabolites to be regulated, then new field trial studies may be needed. A processing study must be conducted for peanuts. Peanuts with detectable residues of the parent and the regulated metabolites should be processed into meal, crude oil, refined oil, and soapstock to determine the residue concentration or reduction factor(s). If the peanuts are treated at exaggerated rates equivalent to at least the maximum theoretical concentration factor due to processing and no detectable residues are found on the rac, then processing studies are not required.
Note: exaggerated rates may be necessary.

Guideline #: 171-4(k/l) Description: Rice field trials/process
Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: N/A
Data Waiver( ) Time Extension( ) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): ___
Discussion:
Registrant has committed in the Phase 3 submission to supply new field trial and processing studies.

Data gap:
Data depicting residues of sodium acifluorfen and the regulated metabolites in/on rice. The 2.0 lbs. a.i./gallon SC/L formulation must be applied postemergence at the maximum label rate of 0.25 lb. a.i./A in one application or in two applications of 0.125 lb. a.i./A each from late tillering to early boot rice growth stages. The PHI must be 50 days. Application should be made aerially in 5 - 10 gallons of water per acre. Analyses must be conducted on grain dust as well as rice grain. The tests must be conducted in AR, CA, LA or MS, TX, and MO which represent the major rice production regions. A processing study must be conducted for rice. Rice with detectable residues of the parent and the regulated metabolites should be processed into polished rice, hulls, and bran to determine the residue concentration or reduction factor(s). If the rice is treated at exaggerated rates equivalent to at least the theoretical concentration factor due to processing and no detectable residues are found on the rac, then processing studies are not required.
Note: exaggerated rates may be necessary.

Guideline #: 171-4(k/l) Description: Soybeans field trials/process

Is requirement applicable? (Y/N): Y
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: P
Data Waiver(X) Time Extension(X) Other ( )
Data Waiver/Time Extension (If applicable) Granted? (Y/N): N
Discussion:
The registrant indicated in the Phase 2 response that the requirement would be met with a previously submitted report and that the supporting data did exist. The registrant now requests continued registration until the transfer of documentation from a former registrant is completed. CBRS contends that no additional time should be needed.
The registrant also requests a waiver from the requirement to provide a soybean processing study. The registrant maintains that field trial data show no residues in/on beans from the application of sodium acifluorfen at 2X - 3X the maximum label rate and that the processing concentration factor is 2X, based on an examination of tolerances for soybeans and soybean processed fractions (40 CFR). CBRS notes that a factor of 20X occurs for the herbicide quizalofop ethyl (40 CFR 186.5250 and 40 CFR 180.441). Moreover, the theoretical maximum concentration factor must be considered. If 10% of the initial soybean weight is converted to soapstock, for example, then the theoretical concentration factor is 10. Also, much of the field trial data is suspect because of excessive PHI's. The registrant does not have adequate field trial data to support the waiver request.
MRID: 92168053; 92168045 Summary.
The summary indicates that 37 trials were conducted in 14 states (IL, IA, AR, IN, MI, OH, LA, SC, GA, TX, OK, MD, NC, and MO). All but 7 of the trials were conducted at or above the maximum label application rate of 1.0 lb. a.i./A/season, but the PHI exceeded the label 50 day PHI in 23 trials (55 - 169 days). Three of the trials utilized aerial application. No parent, acid, ester, or amine analog ($\leq$ 0.01 ppm) was detected in any sample. No forage or hay was analyzed, but the labels contain grazing/feeding restrictions. The trial states in which the PHI was $\leq$ 50 days (MS, NC, AR, LA, MO, GA) represent about 30% of domestic soybean production and, except for MO, the states are in the SE. Additional geographic representation from major soybean production areas are needed, using the maximum application rate and minimum PHI: IL or IN, IA, and MN. The soybean storage stability study is adequate, but storage stability data are needed for processed fractions.

Data gap:
Data depicting residues of sodium acifluorfen and the regulated metabolites in/on soybeans. The 2.0 lbs. a.i./gallon SC/L formulation must be applied in two treatments, 0.25 lb. a.i./A followed by 0.75 lb. a.i./A. The last application (0.75 lb. a.i./A) must be no more than 50 days before harvest (50 day PHI). The use of aerial (10 gallons water/A) and ground (20 gallons water/A) equipment must be represented in separate tests. The tests must be conducted in IL or IN, IA, and MN which represent the major soybean production

regions in addition to those of the present submission.
A processing study must be conducted for soybeans. Soybeans with detectable residues of the parent and the regulated metabolites should be processed into hulls, soapstock, meal, crude oil, and refined oil to determine the residue concentration or reduction factors. If the soybeans are treated at exaggerated rates equivalent to at least the maximum theoretical concentration factor due to processing and no detectable residues are found on the rac, then processing studies are not required.

Note: exaggerated rates may be necessary.

ADDITIONAL COMMENTS:
The registrant is advised to consult the Subdivision O Residue Chemistry Guidelines, the Standard Evaluation Procedures, the Data Reporting Guidelines, and the Phase 3 Technical Guidance concerning conduct of residue chemistry studies. If the registrant has additional concerns they are advised to submit a protocol for CBRS review.

PRODUCT CHEMISTRY

Case No.: 2605 Case Name: Sodium Acifluorfen
Chemical No(s).: 11402
Chemical Name(s): 5-[(2-Chloro-4-triflouormethyl)-phenoxy]-2-nitrobenzoic acid, Sodium salt.
Registrant: BASF Corp.

Guideline Number	Is requirement applicable?	Does summary or available information indicate MRID is a candidate for Phase 5 review?	Are additional data required?	MRID Number
61-1	Y	N/A	Y[a]	
61-2(a)	Y	N/A	Y[a]	
61-2(b)	Y	N/A	Y[a]	
62-1	Y	N/A	Y[a]	
62-2	Y	N/A	Y[a]	
62-3	Y	N/A	Y[a]	
63-2	Y	N/A	Y[a]	
63-3	Y	N/A	Y[a]	
63-4	Y	N/A	Y[a]	
63-5	Y	N/A	Y[a]	
63-6	N			
63-7	Y	N/A	Y[a,b]	
63-8	Y	Y	N	41650302
63-9	Y	N/A	Y[a]	
63-10	Y	N/A	Y[a]	
63-11	Y	N/A	Y[a]	
63-12	Y	N/A	Y[a]	
63-13	Y	Y	N	41650301

Key: Y=yes; N=no; I=a decision cannot be made at this time; S=fully satisfies requirement; P=partially; N/A=not applicable; U=unsatisfactory.

[a] Registrant has committed in Phase 3 submission to provide a new study.

[b] Registrant is reminded that true density (not bulk density) must be determined for the TGAI.