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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Chlorothalonil Reregistration: List A Case No. 0097: Chemical No. 081901: ISK-Bioscience's Submission of Final Report on 6-year Storage Stability Study. MRID Nos. 442405-01 through -10. DP Barcode D235069.

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In response to a reregistration DCI dated 7/31/91, ISK Biosciences Corporation has submitted a final report on a six-year storage stability study concerning chlorothalonil and related residues on almonds, almond hulls, carrots, celery, cherries, cucumbers, potatoes, soybeans, tomatoes and wheat grain.

The Agency has previously reviewed a 4-year interim report on this study (W. Smith, 8/5/94, D194461...), and concluded that chlorothalonil, its metabolites SDS-3701 and SDS-46851, and impurities hexachlorobenzene (HCB) and pentachlorobenzonitrile (PCBN) are stable for four years in frozen samples of carrots, celery, cherries, cucumbers, potatoes, soybeans, tomatoes and wheat grain. Residues on peanuts appeared to decrease at the rate of ca. 9% per year.

The Residue Chemistry Chapter of the Chlorothalonil RED was completed on 6/13/95 (W. Smith, D201522). At that time it was noted that further storage stability data were required; however, these data were expected to be confirmatory to our conclusion that chlorothalonil residues of concern are stable under frozen conditions.



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CONCLUSIONS AND RECOMMENDATIONS

1. The submitted data regarding the storage stability of chlorothalonil, metabolites SDS-3701 and SDS-46851, and impurities hexachlorobenzene (HCB) and pentachlorobenzonitrile (PCBN) on almonds, almonds, carrots, celery, cherries, cucumbers, potatoes, soybeans, tomatoes and wheat over a 6-year period, satisfy storage stability requirements for reregistration purposes. [Guideline 171-4 (e)\OPPTS # 860.1380].
2. Chlorothalonil residues of concern are stable during frozen storage intervals such as incurred in completing field trial residue studies in support of reregistration.

DISCUSSION

ISK Biosciences (MRIDs 42875910-18) submitted data pertaining to the stability of chlorothalonil, its metabolites SDS-3701 and SDS-46851, and the formulation impurities HCB and PCBN in almond hulls and nutmeats, cucumbers, carrots, celery, cherries, peanuts, potatoes, soybeans, tomatoes, and wheat grain in frozen storage.

Field testing, under the direction of ISK Biosciences, was conducted in the states listed in Table 1 using the 6 lb/gal FIC formulation (BRAVO 720). The formulation batch (TMSLOUE) contained 54.2% chlorothalonil, [REDACTED] HCB, and [REDACTED] PCBN.

Table 1. Summary of application rates and field trial locations for storage stability studies performed on almonds, carrots, celery, cherries, cucumbers, peanuts, potatoes, tomatoes, soybeans, and wheat grain.

Commodity (location of field trial)	Application rate (lb/A)	Number of applications	Maximum theoretical seasonal rate ^a
Almonds (CA)	3	13	> 2x
Carrots (WI)	15	11	8x
Celery (WI)	2.25	16	0.8x
Cherries (NY)	3.094	10	2x
Cucumbers (OH)	2.25	3	0.6x
Cucumbers (OH)	6.75	1	--
Peanuts (GA)	9-10.725	11	9x
Potatoes (WI)	11.25	15	15x
Soybeans (MO)	15	8	27x
Tomatoes (OH)	2.25	8	1.1x
Tomatoes (OH)	6.75	1	--
Wheat grain (MO)	11.25	7	NA ^b

^a Maximum theoretical rate based on foliar applications after planting of seedlings.

^b NA = Not applicable; not registered for use on wheat.

A composite sample was harvested for each commodity from both treated and untreated plots. Subsamples of each commodity were randomly taken from the composite harvest. The unhomogenized samples were shipped to Ricerca, Inc., Painesville, OH for storage and analysis. Upon receipt at the analytical laboratory 0-7 days after harvest, two treated samples and one untreated sample were analyzed unfrozen, representing the zero-time sample. The remaining samples were frozen, and two treated and one untreated sample were taken for analysis at intervals beginning after one day. Sample storage temperatures ranged from -23 to -7 C. Residues varied considerably from one sample to another; therefore, the registrant used statistical methods in an attempt to determine if variation was significantly related to time of storage. Regression analyses, assuming both zero order and first order decay processes, were performed.

The currently submitted data represent the final report covering storage intervals up to 6 years. All of the supporting data, as reported in the 4-year interim report, were summarized and tabulated in our previous review (W. Smith, 8/5/94, D194461...). The extension of these data to 6 years is summarized for each crop in the following paragraphs, with emphasis on any additional observations made since the 4-year interval report. The complete 1-year, 4-year and 6-year reports can be found in the submissions listed in Table 2. These reports contain complete documentation of the analytical method, and all parameters relevant to the field study, laboratory analysis, and calculations.

Table 2. Submissions Documenting a 6-Year Storage Stability Study for Chlorothalonil, Metabolites, and Impurities.

CROP	1-Year Interim Report	4-Year Interim Report	6-Year Final Report
Almonds			44240501
Cucumbers	41564825	42875910	44240504
Carrots	41564820	42875911	44240502
Celery	41564822	42875912	44240503
Cherries	41564826	42875913	44240505
Peanuts		42875914	44240506
Potatoes	41564821	42875915	44240507
Soybeans	41564823	42875916	44240508
Tomatoes	41564824	42875917	44240509
Wheat	41564827	42875918	44240510

Stability of Individual Crops under Frozen Storage for Six Years

Almond Hulls and Nutmeats [MRID 44240501]

Chlorothalonil in the almond nutmeats was stable over the 2247 day period of frozen storage. The stability of HCB, PCBN, SDS-3701 and SDS-46851 could not be evaluated since there were no measurable residues. In almond hulls, chlorothalonil, SDS-3701, HCB and PCBN were stable over the 2242 day time period. SDS-46851 levels were too low to be evaluated.

Carrots [MRID 44240502]

Residues of chlorothalonil, SDS-3701, HCB and PCBN were stable in carrots stored for six years under frozen conditions. Residues of SDS-46851 were below the 0.03 ppm limit of detection in all but three of the bags analyzed; therefore, no conclusion could be made concerning its stability.

Celery [MRID 44240503]

Residues of chlorothalonil, SDS-3701, HCB and PCBN were stable in celery stored for six years under frozen conditions. Residues of SDS-46851 were below the 0.03 ppm limit of detection; therefore, no conclusion could be made concerning its stability.

Cucumbers [MRID 44240504]

No residues of HCB were found in samples from the first 5 sampling dates and consequently, the analysis of HCB was discontinued. No residues of SDS-46851 were observed except for one replicate of one sample at 360 days and one replicate of one sample at 727 days. Thirty-four of the seventy-six analyses for SDS-3701 had 0.01-0.02 ppm; the remainder of the samples analyzed had nondetectable residues (<0.01 ppm). No increase in SDS-3701 residues were observed over 6 years.

Regression analysis based on the first 4.5 years of data indicate chlorothalonil declined by 4% per year and PCBN declined by 7% per year. The decline after that time was much more rapid. Declines for the 5-6-year period were 47% for chlorothalonil (6-year decline of 59%) and 38% for PCBN (6 year decline of 68%). Only 3 time intervals were represented in the last 1.5 years. It was recommended that cucumber samples for chlorothalonil residue analysis not be stored longer than 4.5 years.

Cherries [MRID 44240505]

Residues of chlorothalonil, SDS-3701, HCB, and PCBN were stable under frozen conditions over six years of this study. Levels of SDS-46851 were below the limit of detection (<0.03 ppm); therefore, its stability could not be evaluated.

Peanuts MRID [44240506]

Residues of HCB and PCBN in peanut nutmeats were stable under frozen storage conditions for six years. There was a statistically significant downward trend for chlorothalonil, which declined by 35% over the six years of this study. An increase in SDS-3701 and SDS-46851 residues was observed over the 6 year length of the study.

Statistical evidence indicates that HCB, and PCBN are stable over the six year period. Residue levels of chlorothalonil showed a statistically significant downward trend, declining 35% over the six year period. The statistical procedures were used only to detect down trends. In fact SDS-3701 increased from 0.06 ppm to 0.98 ppm and SDS-46851 increased from 0.11 ppm to 0.52 ppm while the chlorothalonil was decreasing from 13 ppm to 9.28 ppm. The chlorothalonil loss cannot be attributed to nonuniform sampling since HCB and PCBN, which are manufacturing impurities and consequently would have been deposited at the same proportional amount as chlorothalonil, were shown to neither increase nor decrease. Therefore, it appears that the peanut nutmeat matrix will in time convert some of the chlorothalonil to its metabolites SDS-3701 and SDS-46851. Since the loss in chlorothalonil is not completely accounted for by the increases in SDS-3701 and SDS-46851 it is not possible to prove from these data that they are stable in peanut nutmeats.

Potatoes [MRID 44240507]

Since residues of HCB were detected in only one of forty-two bags of potatoes analyzed, no conclusions could be made on the stability of HCB. Statistical analysis showed no evidence of a significant downward trend of residues of chlorothalonil, its metabolites SDS-3701 and SDS-46851, and manufacturing impurity PCBN on potatoes stored for six years under frozen conditions.

Soybeans [MRID 44240508]

Residues of chlorothalonil, HCB, PCBN and SDS-3701 were stable in soybeans stored under frozen conditions for six years. Residue levels of SDS-46851 were too low to statistically evaluate its stability in soybeans.

Tomatoes [MRID 44240509]

Residues of chlorothalonil, HCB and PCBN were stable under frozen conditions for six years. A statistically significant downward trend was detected for SDS-3701. Regression analysis indicated that SDS-3701 declined by 30% over the six years. Levels of SDS-46851 were below the limit of detection (0.03 ppm) ; therefore, its stability could not be evaluated.

Wheat [MRID 44240510]

Residues of chlorothalonil, SDS-3701, HCB and PCBN were stable under frozen conditions for six years. Levels of SDS-46851 were below the limit of detection (0.03 ppm) ; therefore, its stability could not be evaluated.

cc: W. Smith (CEB-I), A. Ertman (SRRD/RB), Reg Std File, SF, RF.

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