Data Evaluation Report on the phototransformation of halcomid on soil

PMRA Submission Number {.....} EPA MRID Number 45369734

Data Requirement: PMRA Data Code:
EPA DP Barcode: D284964
OECD Data Point:
EPA Guideline: 161-3

Test Material:
Common name: Halcomid.
Chemical name
IUPAC: N,N-Dimethyldecanoic acid amide.
CAS name: Not reported.
CAS No: Not reported.
Synonyms: None.
SMILES string: O=C(CCCCCCCCC)N(C)C.

Primary Reviewer: Lisa Koterwas **Signature:**
Dynamac Corporation **Date:**

QC Reviewer: Kathleen Ferguson **Signature:**
Dynamac Corporation **Date:**

Secondary Reviewer: Alex Clem **Signature:**
EPA Reviewer **Date:** 23 Dec 2004

Company Code:
Active Code:
Use Site Category:
EPA PC Code: 999999

CITATION: Burri, R. 1996. Photodegradation study of [1-^{14}C]N,N-dimethyldecanoic acid amide on soil. Unpublished study performed by RCC Umweltchemie AG, Itingen/BL, Switzerland, sponsored by Bayer AG, Leverkusen, Germany, and submitted by C. P. Hall Company, Chicago, IL. RCC Project No.: 370247. Study experimental start date June 15, 1994 and study experimental end date August 17, 1995 (p. 15). Final report issued on January 4, 1996.

ADMINISTRATIVE CONCLUSIONS

1) This study has scientific utility, is classified as supplemental, and partially satisfies Subdivision N Guideline criteria for photolysis on soil (§161-3). In spite of numerous study deficiencies, no additional soil photolysis data are needed at this time.

2) The submitter should note the criticism and comments given throughout this Data Evaluation Report (DER), especially Sections III and IV, and consider their applicability to the acceptability of future submissions.

SCIENTIFIC CONCLUSIONS

A reviewer-estimated first-order photolysis half-life in this study for halcomid on soil that was plated thin (approximately 1 mm layer) on glass and irradiated intermittently (12-hour light/12-hour dark cycles) with simulated sunlight (UV-filtered xenon arc lamp) for 30 days is roughly 75 days. Under practical conditions in field soil, photodegradation would be expected to be substantially slower. In a photolysis in water study (MRID 45369737), halcomid was essentially stable, which is generally consistent with its absorption spectrum.

With the possible exception of one anomalous sample at the last sampling interval (30 days posttreatment), no major transformation products were identified. The only minor transformation product was D9 (acid of WAK 7034; N,N-dimethylmalonic acid monoamide), which was isolated only once, at 1.9% of the applied at 30 days posttreatment. Seven unidentified regions of radioactivity were each ≤3.9% of the applied at various sampling intervals. [The anomalous, single 30-day sample was reported to contain 31.5% of the applied radioactivity as D8 (WAK 6747; N,N-dimethylsuccinic acid monoamide), but, as noted elsewhere in this DER, this result is of uncertain/unresolved validity. This product was also present in laboratory aerobic soil metabolism studies.]

EXECUTIVE SUMMARY

The phototransformation of [1-^{14}C]-labeled N,N-dimethyldecanoic acid amide (halcomid) was studied on sandy loam soil (pH 7.9, organic matter 1.4%) from California for 30 days under intermittent irradiation (12-hour light/12-hour dark cycles) at 25 ± 1°C. The soil moisture content was maintained at 75% of 1/3 bar. [^{14}C]Halcomid was applied at a measured concentration of 4.08 mg a.i./kg; equivalent to a field application rate of 600 g a.i./ha at a 1 cm depth. The test systems were irradiated by a UV-filtered xenon arc lamp (300-800 nm; average intensity 92.1 Klux) that was similar in wavelength intensity to natural sunlight in summer on a clear, cloudless day (*ca.* 90-100 KLux). This experiment was conducted in accordance with US EPA Pesticide Assessment Guidelines, Subdivision N §161-3, and in compliance with USEPA Good Laboratory Practices.

The test system consisted of plates of treated soil (glass plate size, 5 cm x 10 cm; soil layer thickness, *ca.* 1.0 mm; average soil weight, 3.230 g per plate) that were placed inside one of two incubation chambers. One chamber (irradiated) was sealed with double-walled quartz glass and maintained inside the photolysis apparatus. The other chamber (dark control) was sealed and maintained in darkness. The chambers were attached to volatile trapping systems; humidified air was continuously forced through a chamber, then through ethylene glycol and NaOH trapping solutions. Duplicate samples were collected at 0, 3, and 14 days posttreatment; single samples were collected at 1, 7 and 30 days.

The samples were extracted at ambient temperatures by shaking with acetonitrile and (except 0 days) methanol:water (1:1 or 2:8, v/v, v/v) and by refluxing with methanol at 70°C. At 30 days, the incubation chambers were washed with water and ethanol. The soil extracts, extracted soils, volatile traps, chamber wash, and nonextractable residues were analyzed for total radioactivity using LSC. The ambient soil extracts were analyzed for halcomid and its transformation products using two one-dimensional TLC systems. Areas of radioactivity on the plates were identified by comparison to reference compounds of halcomid, N,N-dimethyloctanoic acid amide, decanoic acid, decanedioic acid, N,N-dimethylsuccinic acid amide (WAK 6747), and N,N-dimethylmalonic acid amide (Acid of WAK 7034). Identifications were confirmed using HPLC (see attachment for chemical structures of parent and identified products).

Overall [^{14}C]residue recoveries averaged 98.5 ± 1.6% of the applied (range 96.5-101.3%) in the dark controls and 97.4 ± 3.2% (range 91.8-101.3%) in the irradiated soils.

In the dark control samples, [^{14}C]halcomid decreased from an average of 95.7% of the applied at 0 days posttreatment to 92.8% at 14 days and 86.8% at 30 days. No major transformation products were isolated. The only minor transformation product, D8 (WAK 6747; N,N-dimethylsuccinic acid monoamide), was isolated only once, at 1.9% of the applied at 30 days posttreatment. [^{14}C]Extractable residues (ambient plus reflux) decreased from an average 97.5% of applied at 0 days posttreatment to 92.0% at 30 days; [^{14}C]nonextractable residues were 1.2% at 30 days. At 30 days posttreatment, $^{14}CO_2$ and volatile organics totaled 2.0% and <0.05% of the applied, respectively.

In the irradiated samples, [^{14}C]halcomid decreased from an average of 95.7% of the applied at 0 days posttreatment to 81.7% at 14 days and was apparently 19.2% at 30 days (study termination). No major transformation products were isolated through 14 days posttreatment. The single 30-day sample was anomalous; in this sample, D8 (WAK 6747; N,N-dimethylsuccinic acid monoamide) was reported as 31.5% of the applied, but this value is possibly erroneous and of uncertain validity (see Sections III and IV). The only minor transformation product, D9 (Acid of WAK 7034; N,N-dimethylmalonic acid monoamide), was isolated only once, at 1.9% of the applied at 30 days posttreatment. Seven unidentified regions of radioactivity were each ≤3.9% of the applied at all sampling intervals. [^{14}C]Extractable residues (ambient plus reflux) decreased from an average 97.5% of applied at 0 days posttreatment to 92.6% at 14 days, and were 69.5% at 30 days. [^{14}C]Nonextractable residues were variable, totaling ≤3.2% of the applied at all

sampling intervals. At 14 days posttreatment, $^{14}CO_2$ and volatile organics totaled 0.5% and 0.1% of the applied, respectively. At 30 days posttreatment, $^{14}CO_2$ and volatile organics totaled 5.8% and 0.1% of the applied, respectively.

Based on first order linear regression analysis (Excel 2000) and using data through 30 days, [^{14}C]halcomid dissipated with reviewer-calculated half-lives of 14.75 days for the irradiated samples and 301.37 days for the dark controls. However, the accuracy of these data are highly uncertain, since the 30-day irradiated sample (single sample) appears to be an outlier and the half-life of the dark controls is extrapolated far beyond the duration of the experiment. Also, the r^2 values associated with both the irradiated and dark control linear regression lines are <0.80. Using data only through 14 days, the reviewer-calculated half-life for halcomid on irradiated soil is notably longer at 59.75 days with an r^2 of 0.9127.

Using irradiated data through 14 days and dark control data through 30 days, the **phototransformation half-life** for halcomid is approximately 75 days based on the 12-hour light/12-hour dark cycle used in the study, or 37 days based on continuous irradiation.

The intensity of natural sunlight at the vertical in summer on a clear, cloudless day was reported as *ca.* 90-100 KLux, compared to the 92.1 KLux average intensity of the artificial light Therefore, 1 day of artificial light is approximately equivalent to 1 day of natural sunlight. The predicted **environmental phototransformation half-life** of halcomid is therefore equivalent to the phototransformation half-life of approximately 75 days.

The study author repeated the irradiated portion of the experiment as described; data were reported only for 30 days posttreatment. At 30 days posttreatment, halcomid comprised 47.3-53.7% of the applied. The only major transformation product was WAK 6747 (D8) at 7.8 and 15.3% of the applied in duplicate samples. The minor transformation product Acid of WAK 7034 (D9) measured <0.5% of the applied at all sampling interval; six unidentified areas of radioactivity were each ≤4.2% of the applied. [^{14}C]Extractable and [^{14}C]nonextractable residues were 68.6-68.7% and 11.7-10% of applied . $^{14}CO_2$ and volatile organics totaled 16.0% and 0.1% of the applied, respectively, and the chamber wash was 0.5%.

A proposed degradation pathway was provided by the study author. Halcomid was said to degrade to WAK 6747 (N,N-dimethylsuccinic acid monoamide), which then would degrade to the acid of WAK 7034 (N,N-dimethylmalonic acid monoamide), which then would degrade to CO_2 (and presumably other by-products).

Results Synopsis

Soil type: Sandy loam soil.
Source of irradiation: Xenon lamp (12-hour light/12-hour dark cycle).
Half-life for irradiated samples (0-14 day data): 58.75 days (r^2 = 0.9127).
Half-life for dark controls: 301.37 days (r^2 = 0.5872).

Major transformation products/irradiated samples:
None through 14 days (30 day results were not considered valid).
Major transformation products/dark controls:
None.
Minor transformation products/irradiated samples (through 14 days):
Acid of WAK 7034 (N,N-dimethylmalonic acid monoamide).
CO_2.
Minor transformation products/dark controls:
WAK 6747 (N,N-Dimethylsuccinic acid monoamide).
CO_2.

Study Acceptability: This study is classified as **supplemental**. The data for the irradiated samples through 14 days posttreatment appear to be valid, but the reviewer has serious doubt about the validity of the 30-day irradiated sample data. The study does not meet the requirements for a photodegradation in water study because valid data were provided only through 14 days. In addition, [^{14}C]residues that were washed from the walls of the incubation chamber for the irradiated samples at 30 days (14.7% of the applied radioactivity) were not characterized.

I. MATERIALS AND METHODS

The page numbers which are referenced in the DER correspond to the page numbers which are found in the lower right-hand corner of the study report. The page numbers which appear at the top right-hand corner were not followed because they did not include all of the pages in the study report.

GUIDELINE FOLLOWED: This study was conducted in accordance with USEPA Pesticide Registration Guideline Subdivision N §161-3 and amendments (pp. 1, 16). No significant deviations from Subdivision N guidelines were noted in the 0-14 day portion of the experiment. However,

> The single 30-day irradiated sample that was collected in the main study appeared to be an outlier when compared to earlier sampling intervals and a supplementary experiment. This uncertainty does affect the validity of the 30-day data.
>
> At 30 days, up to 14.7% of the applied radioactivity was washed from the sides of the chamber holding the irradiated samples but these residues were not characterized. This does not affect the validity of the study.

COMPLIANCE: This study was conducted in compliance with USEPA, OECD, and Swiss Good Laboratory Practices (1989; 1981; 1986, respectively; pp. 4, 16). Signed and dated Data Confidentiality, GLP, Certificate of Authenticity, and Quality Assurance statements were provided (pp. 2-4, 7-8).

A. MATERIALS:

1. Test Material: [1- ^{14}C]Halcomid (pp. 19-20).

Chemical Structure: See DER Attachment.

Description: Colorless liquid (nonradiolabeled; p. 19).

Purity: Radiochemical purity: 98.6% (average prior to experiment; p. 20).
Batch No.: A387/1.
Analytical purity: Not reported.
Specific activity: 100.5 µCi/mg (3.72 MBq/mg).
Location of the radiolabel: 1-Carbon (carbonyl carbon).

Storage conditions: The test substance was stored in the dark at *ca.* -20°C (p. 20).

Physico-chemical properties of halcomid (N,N-dimethyldecanoic acid amide).

Parameter	Values	Comments
Molecular Formula	Not reported.	
Molecular weight	199.4 g/mole.	
Water solubility	270 mg/L.	At 20°C and pH 5.5.
Vapor pressure	Not reported.	
UV absorption	Not reported.	
pK_a	Not reported.	
K_{ow}/log K_{ow}	Not reported.	
Stability of compound at room temperature	Not reported.	

Data obtained from p. 19 of the study report.

2. Soil Characteristics:

Table 1: Field information and handling procedures.

Information	Details
Geographic location	Porterville, California, USA.
Site description	Not reported.
Pesticide use history at the collection site	Not reported.
Collection procedures	Not reported.
Collection date	December 1991.
Sampling depth (cm)	Not reported.
Storage conditions	When received at the testing facility, the soil was placed outdoors in boxes *(ca.* 10 cm depth) and native vegetation was allowed to grow on the surface. During winter months, the soil was stored indoors (moisture maintained) at room temperature under artificial light. Prior to study, the soil was transferred into plastic bags and stored indoors at room temperature.
Storage length	*ca.* 3 years at RCC facility (December 1991 to October 17, 1994) for the "initial" study and 3.5 years for the "additional samples".
Soil preparation	Sieved (2 mm).

Data obtained from pp. 22-23 of the study report.

Table 2: Properties of the soil.

Property		Details
Soil texture (USDA):		Sandy loam
% sand (>0.05-2.0 mm)		67.2
% silt (0.002-0.05 mm)		24.6
% clay (<0.002 mm)		8.2
pH in H_2O in KCl		7.90 7.73
Organic matter (%)		1.40
Organic carbon (%)		0.81
CEC (meq/100 g)		5.3
Maximum water holding capacity at 15 bar (%)		Not reported.
Maximum water holding capacity at 1/3 bar (%)		11.43 (reviewer-calculated based on WHC at 75% of 1/3 bar).
Maximum water holding capacity at 75% of 1/3 bar (%)		8.57
Bulk density, disturbed (g/cm^3)		Not reported.
Microbial biomass (colonies/g soil):	Initial	2.5×10^{-6}
	Final irradiated	8.5×10^{-6}
	Final dark control	4.0×10^{-6}
Soil Taxonomic classification		Not reported.
Soil mapping unit (for EPA)		Not reported.

Data obtaioed from p. 24 of the study report.

3. Details of light source:

Table 3: Artificial light source.

Property	Details
Type of lamp used:	Xenon arc lamp (Original Hanau Suntest apparatus).
Emission wavelength spectrum:	290-800 nm
Light intensity:	Average 92.1 KLux at 370-790 nm or 22.2 W/m^2 at 300-400 nm.
Filters used:	UV filters eliminated radiation <290 nm.
Relationship to natural sunlight:	The intensity of natural sunlight in summer on a clear, cloudless day with a vertical incidence of the sun was reported to be *ca.* 90-100 KLux. Therefore, 12 hours of irradiation (or one 12-hour light/12-hour dark cycle) is approximately equivalent to 1 day of natural sunlight. The spectral energy distributions of the artificial light at test initiation and termination were provided in Figures 3-4, pp. 53-54. A direct comparison of the artificial light to natural summer sunlight was provided in Figure 2, p. 52 of the study report.

Data obtained from pp. 22 and 29, and Figures 1-4, pp. 51-54 of the study report.

B. EXPERIMENTAL DESIGN

1. Preliminary Study: A "first study" was initiated on June 27 and terminated on July 8, 1994 because of "incomplete balances" (p. 22). The experiment was not described, and any modifications that might have been made to the "initial study" as a result of lessons learned were not identified.

2. Experimental Design

Table 4: Experimental design.

Parameter	Details
Duration of the test	30 days
Condition of soil (Air dried/fresh):	Fresh (air-dried enough for sieving).
Test concentration (mg a.i./kg soil): Nominal Measured	 4 mg a.i./kg , equivalent to a field application rate of 600 g/ha at a 1 cm depth. 4.08 mg a.i./kg.
Dark controls used:	Yes
Method to maintain darkness:	Samples were contained in a metal chamber with light excluded.

Parameter		Details
Replications	Irradiated:	Two plates of soil were collected at day 0. At later intervals, only one plate of soil was collected. However, the plates that were sampled at 14 days were divided into two sections prior to treatment, and these two sections were treated independently so that the two sections served as replicates (A and B).
	Dark control:	
Identity and concentration of co-solvent:		Acetonitrile, *ca.* 2% (760 µL of a solution containing 10% acetonitrile to *ca.* 3.23 g soil).
Pesticide application	Volume of test solution used/treatment	760 µL/plate or 380 µL/half-plate; a plate contained *ca.* 3.23 g soil.
	Method of application	Not reported.
	Is the co-solvent evaporated?	No.
Test apparatus: Type/Material/ Volume	Preparation of soil plates	A slurry of the test soil was spread over 16 gluss plates (5 cm x 10 cm, *ca.* 3.23 g soil/plate dry weight) and adjusted to a thickness of *ca.* 1.0 mm. The plates were dried overnight. The soil layer on four of the plates was scored into two equal halves.
	Irradiated	Six of the treated soil plates (including two scored plates) were placed inside a metal chamber (size not specified), which was sealed with a double quartz glass lid and connected to a flow through volatile trapping apparatus. A water jacket surrounding the chamber maintained the soil at 25 ± 1°C. An illustration of the apparatus was provided in Figure 1, p. 51 of the study report.
	Dark controls	Six of the treated soil plates were placed inside a dark metal chamber (size not specified), which was sealed and connected to a flow through volatile trapping apparatus. A water jacket surrounding the chamber maintained the soil at 25 ± 1°C.
Details of traps for volatiles, if any		Moistened air was pumped through the irradiated or dark control chamber then through NaOH and ethylene glycol trapping solutions. The air flow rate was 30 mL/minute; increased to 100 mL/minute 30 minutes prior to opening.
If no traps were used, is the system closed/open?		A volatile trapping system was used.
Any indication of the test material adsorbing to the walls of the test apparatus?		None.

Parameter		Details
Experimental Conditions	Temperature:	Irradiated: 25 ± 1°C (brief temperature fluctuations *ca.* 22.0-29.0°C). Dark: 25.0 ± 0.1°C.
	Temperature maintenance method:	The incubation chambers were cooled via a waterjacket that surrounded the base of the chambers and continued through the quartz glass cover. The temperature of the soil was monitored using a temperature probe inserted into the soil on a reserve plate.
	Moisture content: Moisture maintenance method:	75% of 1/3 bar. Soil samples were moistened every 1-3 days with an amount of water equal to the weight lost in reserve soil plates.
	Duration of light/darkness:	12-hour dark/12-hour light cycle.
Other details, if any		None

Data obtained from pp. 25-28, 30; Table 1, p. 44; and Figure 1, p. 51 of the study report.

3. Supplementary experiments: Additional soil plates were prepared, treated (average measured treatment rate 3.91 mg a.i./kg), and incubated as described for the "initial study" (pp. 22, 25, 26, 28; Table 2, p. 45). During the study, the average intensity of the irradiation apparatus was 93.4 Klux (p. 29). Two irradiated and two dark control soil plates were collected at 0, 14, and 30 days posttreatment. Samples were collected and analyzed as described in the definitive study.

4. Sampling:

Table 5: Sampling details.

Criteria	Details
Sampling intervals	0, 1, 3, 7, 14, and 30 days.
Sampling method	Two entire plates of soil were collected for analysis immediately posttreatement. One entire irradiated and one entire dark control plate were collected at 1, 3, 7, 14, and 30 days posttreatment.
Method of sampling CO_2 and volatile organic compounds	The trapping solutions were collected and replaced with fresh solution at every sampling interval.
Sampling intervals/times for: Sterility check, if any: Moisture content: Temperature:	 The soils were not sterile. The soil moisture content was checked at 1-3 day intervals. Soil temperatures were monitored continuously.
Sample storage before analysis	Aliquots of samples were analyzed immediately via LSC and TLC. Samples were stored at *ca.* - 20°C for 4 months prior to HPLC analysis.
Other observations, if any	None.

Data obtained from pp. 26, 28, 30, and 38; and Table 3, p. 46 of the study report.

C. ANALYTICAL METHODS

Extraction/clean up/concentration methods: At the time of sampling, the soil was scraped from the glass plate (not further described). The soil from the 0 day samples was extracted three times with acetonitrile (*ca.* 3 mL/g soil) by shaking at ambient temperatures (p. 30). Samples collected at 1, 3, 7, and 14 days posttreatment were extracted three times with acetonitrile, then once or twice with methanol:water (1:1, v/v). The soil from the 30 day samples was further extracted once with methanol:water (2:8, v/v). Following the ambient extractions, all samples except 0 days were refluxed with methanol at 70°C for 16 hours. After each extraction, the mixture was centrifuged and the supernatant decanted and filtered; aliquots of the individual extracts were analyzed using LSC. The ambient extracts were combined (not described) and analyzed for specific compounds using TLC; selected extracts were analyzed by HPLC.

At study termination, the irradiated and dark control chambers were washed with bidistilled water and ethanol. The chamber wash was analyzed for total radioactivity by LSC. The study author stated that the intention was to analyze the chamber wash of the irradiated samples, but the sample was "accidentally eliminated after radioactivity determination before TLC-analysis" (p. 37).

Nonextractable residue determination: The extracted soils were air-dried at room temperature and ground, then portions were analyzed by LSC following combustion (p. 30).

Volatile residue determination: Aliquots of the NaOH and ethylene glycol solutions were analyzed by LSC for total radioactivity (p. 31). [^{14}C]Residues in the NaOH trap were identified as $^{14}CO_2$ by precipitation with barium hydroxide.

Total ^{14}C measurement: For 0-14 days, the overall [^{14}C]residue recoveries were calculated by summing the concentration of [^{14}C]residues in the soil extracts, extracted soil, and volatile traps. For 30 days, the overall [^{14}C]residue recoveries were calculated by summing the concentration of [^{14}C]residues in the soil extracts, extracted soil, volatile traps, and chamber wash.

Derivatization method: A derivatization method was not employed.

Identification and quantification of the parent: Halcomid in the ambient extract was separated, quantified, and identified by one-dimensional TLC on silica gel plates (5 cm x 20 cm; 0.25 mm thickness; 60 F_{254}) developed in chloroform:acetonitrile (50:50, v:v; solvent system code: SS 6) or chloroform:acetonitrile:acetic acid (50:50:2, v:v:v; solvent system code: SS 7; p. 32). The SS 7 solvent system was used to separate [^{14}C]residues which occurred near the origin when using the SS 6 solvent system. The samples were cochromatographed with an unlabeled reference standard of halcomid (purity 98.8%; SS 6 R_f 0.86; SS 7 R_f 0.85; pp. 19, 32-33). The plates were visualized by exposure to iodine and UV light (254 nm); radioactive areas were quantified by autoradiography.

The results of the TLC analysis were confirmed using HPLC under the following conditions (pp. 34-35): Lichrospher RP 18 column (250 mm x 4.0 mm; 5 µ), mobile gradient phase consisting of (A) acetonitrile and (B) bidistilled water [A:B, v:v; 0-5 minutes 0:100, 25-30 minutes 100:0, and 30.1-40 minutes 0:100], with UV (205 nm) and radioactivity detection. Halcomid was identified by comparison to the retention time of an unlabeled reference standard (purity 98.8%; Rt 25.10 minutes).

Identification and quantification of transformation products: The transformation products were isolated and quantified by TLC as described for the parent, except that spraying the plates with bromocresol green/bromophenol blue/potassium permanganate was also used for visualization (pp. 32-33). The retention times of transformation products were compared to the retention times of the following unlabeled reference standards (pp. 21, 33; only WAK 6747 and Acid of WAK 7034 were cochromatographed with the soil extracts):

Reference Compound	Ref. Code	Purity (%)	Rf- TLC (SS 6)	Rf- TLC (SS 7)
N,N-Dimethyldecanoic acid amide	None	98.8	0.86	0.85
N,N-Dimethyloctanoic acid amide	A	97.0	0.82	0.81
Decanoic acid	B	>98	0.56-0.72	0.79
Decanedioic acid	C	>98	0.07	0.58
N,N-Dimethylsuccinic acid monoamide	WAK 6747	92.8	0.01-0.08	0.26
N,N-Dimethylmalonic acid monoamide	Acid of WAK 7034	Not reported	0.00	0.18

The identities of transformation products were confirmed via HPLC as described for the parent (pp. 34-35). The retention times of transformation products were compared to the retention times of the following unlabeled reference standards (pp. 21, 34-35):

Reference Compound	Ref. Code	Purity (%)	Retention time- HPLC
N,N-Dimethyldecanoic acid amide	None	98.8	25.10 minutes
N,N-Dimethyloctanoic acid amide	A	97.0	22.21 minutes
Decanoic acid	B	>98	24.15 minutes
Decanedioic acid	C	>98	17.21 minutes
N,N-Dimethylsuccinic acid monoamide	WAK 6747	92.8	2.10 minutes

Detection limits (LOD, LOQ) for the parent: The Limits of Detection were not reported. The counting error of the LSC was reported to be <5%; more specific data were not provided (p. 31). The reviewer noted that the value of < 0.05% was reported as a LOQ for the LSC in Tables 4-5, pp. 47-48. The Limits of Quantification for the TLC and HPLC were *ca.* 0.5% and 3.3% of the applied radioactivity, respectively (pp. 32, 34).

Detection limits (LOD, LOQ) for the transformation products: The Limits of Detection were not reported. The Limits of Quantification were the same as those for the parent.

II. RESULTS AND DISCUSSION:

A. TEST CONDITIONS: The soils were generally maintained at a temperature of 25 ± 1°C; the study author noted that the temperature of the soil would rise or fall briefly when the lamp was turned on and off, respectively (p. 30). The soil moisture content was maintained at 75% of 1/3 bar (p. 27; Table 3, p. 46).

B. MASS BALANCE: Total [^{14}C]residue recoveries averaged 98.5 ± 1.6% (range 96.5-101.3%) of the applied in the dark controls and 97.4 ± 3.2% (range 91.8-101.3%) in the irradiated samples (Tables 4-5, pp. 47-48). There was no pattern of loss in the dark controls. There was some loss of radioactivity with time in the irradiated samples which may have been related to volatilized residues adsorbing to the sample chamber walls rather than being captured in the volatile trapping system. In the irradiated samples, the concentration of residues without the addition of the chamber wash decreased from 98.9-101.3% of the applied at 0 days posttreatment to 91.8-95.7% at 14 days. At 30 days posttreatment, the only interval at which residues on the chamber walls were measured, [^{14}C]residue recoveries were 78.6% of the applied without the chamber wash and 93.3% with the chamber wash.

Table 6: Phototransformation of [^{14}C]halcomid, expressed as percentage of the applied radioactivity, in irradiated and dark control soil samples (mean ± s.d when n = 2).*

Compound		Rf [1]		Sampling times (days)					
		SS 6	SS 7	0	1 [2]	3	7 [2]	14	30 [2]
Parent (D1, halcomid)	Irradiated	0.80	0.82	95.7 ± 1.3	95.2	92.9 ± 1.6	87.4	81.7 ± 4.0	19.2
	Dark	0.80	0.81		92.4	91.9 ± 0.3	90.7	92.8 ± 1.1	86.8
Unknown D2	Irradiated	0.67	0.71	ND	ND	ND	0.9	2.6 ± 0.2	1.2
Unknown D3	Irradiated	0.57	0.65		ND	<1.4 [3]	2.1	2.8 ± 0.6	1.6
Unknown D4	Irradiated	0.95	0.95	1.9 ± 0.2	1.8	2.3 ± 0.3	3.1	2.6 ± 0.1	1.0
	Dark	0.95	0.95		1.2	1.1 ± 0.2	1.5	<1.9	0.7
Unknown D5	Irradiated	0.34	0.54	ND	ND	ND	ND	1.2 ± 0.2	3.9
Unknown D6	Irradiated	0.25	0.42	ND	ND	ND	ND	ND	2.0
Unknown D7	Irradiated	0.08	0.19	ND	ND	ND	ND	ND	2.6
Unknown D8 (WAK 6747)	Irradiated	0.01	0.28	ND	ND	ND	ND	ND	31.5
	Dark	0.01	0.29		ND	ND	ND	ND	1.9
Unknown D9 (Acid of WAK 7034)	Irradiated	0.01	0.12	ND	ND	ND	ND	ND	1.9
Unknown D10	Irradiated	0.01	0.01	ND	ND	ND	ND	ND	1.9
Total ambient extractable	Irradiated	NA		97.5 ± 1.6	97.0	95.9 ± 0.8	93.5	90.7 ± 2.9	66.8
	Dark	NA			93.6	93.0 ± 0.5	92.2	93.8 ± 0.2	89.4

Compound		Rf [1]		Sampling times (days)					
		SS 6	SS 7	0	1 [2]	3	7 [2]	14	30 [2]
Reflux at 70°C	Irradiated	NA		NS	1.7	2.9 ± 0.0	3.2	1.9 ± 0.2	2.7
	Dark	NA			2.8	3.1 ± 0.3	3.3	3.7 ± 0.1	2.6
Nonextractable	Irradiated	NA		2.6 ± 0.1	0.3	0.6 ± 0.1	0.7	0.7 ± 0.1	3.2
	Dark	NA			0.6	0.7 ± 0.1	0.8	1.2 ± 0.2	1.2
$^{14}CO_2$	Irradiated	NA		NS	0.1	0.1 ± 0.0	0.3	0.5 ± 0.0	5.8
	Dark	NA			0.2	0.4 ± 0.0	0.5	1.1 ± 0.0	2.0
Ethylene gycol	Irradiated	NA		NS	< 0.05	0.1 ± 0.0	0.1	0.1 ± 0.0	0.1
	Dark	NA			< 0.05	< 0.05	< 0.05	< 0.05	< 0.05
Chamber wash [4]	Irradiated	NA		--[4]	--[4]	--[4]	--[4]	--[4]	14.7
	Dark	NA			--[4]	--[4]	--[4]	--[4]	3.2
Total % recovery	Irradiated	NA		100.1 ± 1.7	99.1	99.6 ± 0.8	97.8	93.8 ± 2.8	93.3
	Dark	NA			97.2	97.2 ± 0.9	96.8	99.7 ± 0.6	98.4

* Means and standard deviations calculated by the reviewer. Irradiated data were obtained from Table 4, p. 47 (extractable and nonextractable residues, volatiles, chamber wash, and total radioactivity) and Table 6, p. 49 (residue characterization) of the study report. Dark control data were obtained from Table 5, p. 48 (extractable and nonextractable residues, volatiles, chamber wash, and total radioactivity) and Table 7, p. 50 (residue characterization) of the study report.

1 The retention times were obtained from the day 30 samples.

2 Only one sample was analyzed at 1, 7, and 30 days posttreatment ($n = 1$).

3 Unknown D3 was not detected in replicate A.

4 The chamber was not washed until 30 days posttreatment, and the data were only summed with the 30-day total.

NA= Not applicable.

ND= Not detected.

NS= Not sampled.

C. TRANSFORMATION OF PARENT COMPOUND: In the dark control samples, [^{14}C]halcomid decreased from an average of 95.7% of the applied at 0 days posttreatment to 92.8% at 14 days and 86.8% at 30 days (Table 7, p. 50). In the irradiated samples, [^{14}C]halcomid decreased from an average of 95.7% of the applied at 0 days posttreatment to 81.7% at 14 days and was 19.2% at 30 days (study termination; Table 6, p. 49).

Half-lives: Based on first order linear regression analysis (Excel 2000) and using data through 30 days, [^{14}C]halcomid dissipated with reviewer-calculated half-lives of 14.75 days for the irradiated samples and 301.37 days for the dark controls. However, the accuracy of these data are highly uncertain, since the 30-day irradiated sample (single sample) appears to be an outlier (see Study Deficiencies) and the half-life of the dark controls is extrapolated far beyond the duration of the experiment. Also, the r^2 values associated with both the irradiated and dark control linear regression lines are <0.80. Using data only through 14 days, the reviewer-calculated half-life for halcomid on irradiated soil is notably longer at 59.75 days.

The reviewer-calculated half-life for halcomid in irradiated soil is significantly different from the 33.0 day half-life calculated by the study author using first-order reaction kinetics because the study author substituted the supplemental ("additional samples") 30-day irradiated sample data (47.3 and 53.7% for duplicate samples) for the "initial study" 30-day sample data (19.2%, single sample) in his half-life calculations (pp. 36-37, 42).

Half-lives/DT50s*

Test system	First order linear			DT50 (days)	DT90 (days)
	Half-life (days)	Regression equation	r^2		
Irradiated (0-14 day data only)	59.75	y = -0.0116x + 4.5629	0.9127	33.0	ND
Dark (0-30 day data)	301.37	y = -0.0023x + 4.5429	0.5872	>> 30	ND

* Half-lives were calculated by the reviewer using data obtained from Tables 6-7, p. 49-50 of the study report. DT50s were calculated by the study author (pp. 42-43); the study author's decay curves were illustrated in Figure 32, p. 82 of the study report.
ND = Not determined.

The effective first-order phototransformation rate constant for halcomid is determined by taking the difference between the first-order rate constants (not half-lives) for the irradiated and dark control samples, and converting the difference into the effective first-order half-life ($T_{1/2}$), as indicated by the following equations, where each respective rate constant k equals ln(2) divided by the corresponding half-life.

$T_{1/2}$ = (Ln 2) ÷ [(Ln2/ irradiated half-life) - (Ln 2/dark control half-life)],

or, equivalently and more simply,

$T_{1/2}$ = [(irradiated half-life) x (dark control half-life)] ÷ (dark control half-life - irradiated half-life).

Thus, the effective first-order phototransformation half-life is approximately 75 days based on the 12-hour light/12-hour dark cycle used in the study, or 37 days based on continuous irradiation.

The intensity of natural sunlight at the vertical in summer on a clear, cloudless day was reported as *ca.* 90-100 KLux, compared to the 92.1 KLux average intensity of the artificial light Therefore, 1 day of artificial light is approximately equivalent to 1 day of natural sunlight. The predicted **environmental phototransformation half-life** of halcomid is therefore equivalent to the phototransformation half-life of approximately 75 days.

TRANSFORMATION PRODUCTS: In the dark control soil, no major transformation products were isolated (Table 7, p. 50). One minor transformation product, D8 (WAK 6747; N,N-dimethylsuccinic acid monoamide), was isolated only once, at 1.9% of the applied at 30 days posttreatment. Unknown D4, at ≤2.0% of the applied, may have been a contaminant of the test substance since the maximum concentration was at 0 days.

In the irradiated soil, no major transformation products were isolated through 14 days posttreatment (Table 6, p. 49). In the single 30-day sample which is of uncertain validity, D8 was 31.5% of the applied. One minor transformation product, D9 (Acid of WAK 7034; N,N-dimethylmalonic acid monoamide), was isolated only once, at 1.9% of the applied at 30 days posttreatment. Seven unidentified regions of radioactivity were each ≤3.9% of the applied at all sampling intervals.

Table 7. Chemical names and CAS numbers for the transformation products of halcomid.

Applicant's Code Name	CAS Number	Chemical Name	Chemical formula	Molecular weight (g/mol)	SMILES string
WAK 6747	--	N,N-Dimethylsuccinic acid monoamide	--	--	--
Acid of WAK 7034	--	N,N-Dimethylmalonic acid monoamide	--	--	--

Data obtained from p. 21 of the study report.
-- Not reported.

NONEXTRACTABLE AND EXTRACTABLE RESIDUES: In the dark controls, [^{14}C]extractable residues (ambient plus reflux) decreased from an average 97.5% of applied at 0 days posttreatment to 92.0% at 30 days; [^{14}C]nonextractable residues decreased from 2.6% of the applied at 0 days to 1.2% at 30 days (Table 5, p. 48).

In the irradiated soil, [^{14}C]extractable residues (ambient plus reflux) decreased from an average 97.5% of applied at 0 days posttreatment to 92.6% at 14 days, and were 69.5% at 30 days (Table 4, p. 47). [^{14}C]Nonextractable residues were variable, totaling ≤3.2% of the applied at all sampling intervals.

VOLATILIZATION: In the dark control soil at 30 days posttreatment, $^{14}CO_2$ and volatile organics totaled 2.0% and <0.05% of the applied, respectively (Table 5, p. 48).

In the irradiated soil at 14 days posttreatment, $^{14}CO_2$ and volatile organics totaled 0.5% and 0.1% of the applied, respectively (Table 4, p. 47). At 30 days posttreatment, $^{14}CO_2$ and volatile organics totaled 5.8% and 0.1% of the applied, respectively.

TRANSFORMATION PATHWAY: A degradation pathway was provided by the study author (Figure 33, p. 83). Halcomid degrades to WAK 6747 (N,N-dimethylsuccinic acid monoamide), which degrades to the Acid of WAK 7034 (N,N-dimethylmalonic acid monoamide), which degrades to CO_2.

D. SUPPLEMENTARY EXPERIMENT-RESULTS: Although the study author stated that the repeated experiment was sampled at 0, 14, and 30 days posttreatment, data were reported only for the 30 day samples. At 30 days posttreatment, halcomid comprised 47.3-53.7% of the applied (Table 6, p. 49). The only major transformation product was WAK 6747 (D8) at 7.8 and 15.3% of the applied in duplicate samples. The minor transformation product Acid of WAK 7034 (D9) measured <0.5% of the applied at all sampling interval; six unidentified areas of radioactivity were each ≤4.2% of the applied. Also at 30 days posttreatment, [^{14}C]extractable and [^{14}C]nonextractable residues were 68.6-68.7% and 11.7-10% of applied radioactivity, respectively (Table 4, p. 47). $^{14}CO_2$ and volatile organics totaled 16.0% and 0.1% of the applied, respectively, and the chamber wash was 0.5% (reviewer estimates, since the page was not copied correctly and the decimal places for one of the two samples was lost).

III. STUDY DEFICIENCIES:

1. The dark control portion of this study through 30 days and the irradiated portion of this study through 14 days are scientifically valid and meet guideline requirements. However, in comparing the 0-14 day irradiated data to the 30-day irradiated data from the "initial study" and also comparing the 30-day data from this study to the 30-day data from "additional samples", it appears that the system was corrupted and the 30-day sample is not representative of the behavior of halcomid in irradiated soil. The reason for the change in the behavior of halcomid in the irradiated samples between 14 and 30 days could not be determined from the data provided by the study author. In two aerobic soil metabolism studies submitted in this data package (MRID 45369735 and 45369736), halcomid degrades with a half-life of <1 day. The study author stated that the experiment was repeated because the 30-day chamber wash was not analyzed, disregarding the fact that significantly different

results were obtained in the repeat experiment. It is clear from the data that in the initial experiment, the volatile trapping system failed after 14 days, since volatiles were recovered from the chamber wall and not in the trapping solutions.

2. [^{14}C]Residues that were washed from the walls of the irradiated incubation chamber at study termination totaled 14.7% of the applied radioactivity but were not characterized. The study author stated that the sample was inadvertently discarded prior to TLC analysis (p. 37).

IV. REVIEWER'S COMMENTS

1. As noted at the beginning of the DER, the reviewer referenced the page numbers which are found in the lower right-hand corner of the study report and not those which appear at the top right-hand corner. The reviewer noted that approximately one-half of the page numbers in the lower right-hand corner were not visible due to improper reproduction of the study report by the registrant. As a rule, these numbers are two pages greater than those which appear at the top right-hand corner (which were not followed because they did not include all of the pages in the study report, namely the first three pages).

2. In discussing the study results, the study author made two significant deviations from the norm:

   The study author disregards the results for the 30-day irradiated sample from the main experiment and substituted the results of the repeat experiment without demonstrating that the two experiments were, in fact, comparable. In the discussion of the study conclusions and halcomid half-life, the study author does not mention that the data are from two experiments.

   The study author defined the "bound" fraction as those residues that were not extracted from the soil by shaking at ambient temperatures, and the residues that were extracted during refluxing were reported as a fraction of the bound. However, residues extracted by refluxing are typically considered to be extractable and are discussed as such in this DER.

3. The study author reported that the sandy loam soil was the same soil which was used in the aerobic soil metabolism study for halcomid (RCC Project No.: 340334; p. 17). WAK 6747 (N,N-dimethylsuccinic acid monoamide) was identified in that metabolism study.

4. The numerical/quantitative results of the HPLC analyses which confirmed the identity of the parent were not provided in the study report.

5. The reviewer did not understand the reason that all of the reference compounds were not co-chromatographed with the aqueous solutions, especially in cases that the R_f of an unidentified transformation product was close to that of a reference compound (e.g. D2, SS 6 $R_f = 0.67$,

SS 7 R_f = 0.71; decanoic acid, SS 6 R_f = 0.56-72, SS 7 R_f = 0.79; p. 33; Table 6, p. 49). However, these transformation products did not exceed 4% of the applied radioactivity.

6. The target application rate (4 mg a.i./kg dry soil) was based on the application rate of halcomid (600 g a.i./ha) at a depth of 1 cm and a soil density of 1.5 g/cm^3 (p. 25).

7. The aliquots of the soil extracts which were taken for HPLC analysis (unspecified) were stored at - 20°C for 4 months (p. 38). Storage stability was confirmed by the study author by reanalyzing the soil extract of the 30-day sample A after 3 months of storage at - 20°C. The parent accounted for 47.3% of the applied before storage and 50.1% after storage; WAK 6747 accounted for 15.3% before storage and 14.1% after storage.

8. The Limits of Detection for the LSC, TLC, and HPLC methods were not reported. LODs should be reported to allow the reviewer to evaluate the adequacy of the test method.

9. The physico-chemical properties of the test substances such as vapour pressure, UV adsorption, pK_a, and K_{ow} were not provided.

10. Representative TLC chromatograms were presented in Figures 5-6, pp. 55-56, Figure 8, p. 58, Figures 11-18, pp. 61-68 (irradiated samples), and Figures 21-25, pp. 71-75 (dark controls) of the study report. Representative HPLC chromatograms were presented in Figure 7, p. 57, Figures 26-28, pp. 76-78 (irradiated samples), and Figures 29-30, pp. 79-80 (dark controls) of the study report. Figures 5-8 contained the TLC and HPLC chromatograms of the halcomid stock solution and application solution.

11. The reviewer believed that a typographical error existed on p. 26 of the study report where the study author reported that "6 plates were **continuously** illuminated". The fact that the irradiated samples were exposed to intermittent irradiation (12-hour light/12-hour dark cycles) was reported throughout the study report (pp. 17-18, 27, and 42-43).

V. REFERENCES:

1. U.S. Environmental Protection Agency. 1982. Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate, Section 161-3. Phototransformation studies. Office of Pesticide and Toxic Substances, Washington, DC. EPA 540/9-82-021.

2. U.S. Environmental Protection Agency. 1989. FIFRA Accelerated Reregistration, Phase 3 Technical Guidance. Office of the Prevention, Pesticides, and Toxic Substances, Washington, DC. EPA 540/09-90-078.

3. U.S. Environmental Protection Agency. 1993. Pesticide Registration Rejection Rate Analysis - Environmental Fate. Office of the Prevention, Pesticides, and Toxic Substances, Washington, DC. EPA 738-R-93-010.

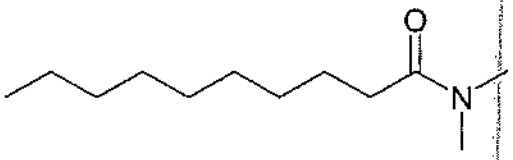
ATTACHMENT

Chemical Structures of Parent, Transformation Products, and Undetected Reference Compounds

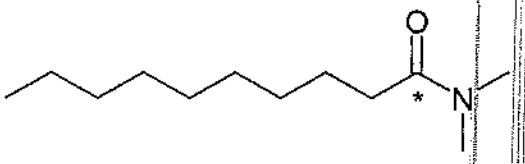
Halcomid

IUPAC name: N,N-Dimethyldecanoic acid amide.
CAS name: Not reported.
CAS No: Not reported.
SMILES string: O=C(CCCCCCCCC)N(C)C

Unlabeled



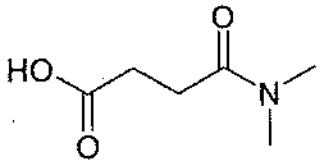
[1-^{14}C]Halcomid



* Position of radiolabel.

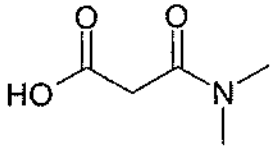
WAK 6747

IUPAC name: Not reported.
CAS name: N,N-dimethylsuccinic acid monoamide.
CAS No: Not reported.



Acid of WAK 7034

IUPAC name: Not reported.
CAS name: N,N-dimethylmalonic acid monoamide.
CAS No: Not reported.



Undetected Reference Compounds

N,N-Dimethyloctanoic acid amide
Structure not provided.

Decanoic acid
Structure not provided.

Decanedioic acid
Structure not provided.

Attachment 1

Excel Spreadsheets

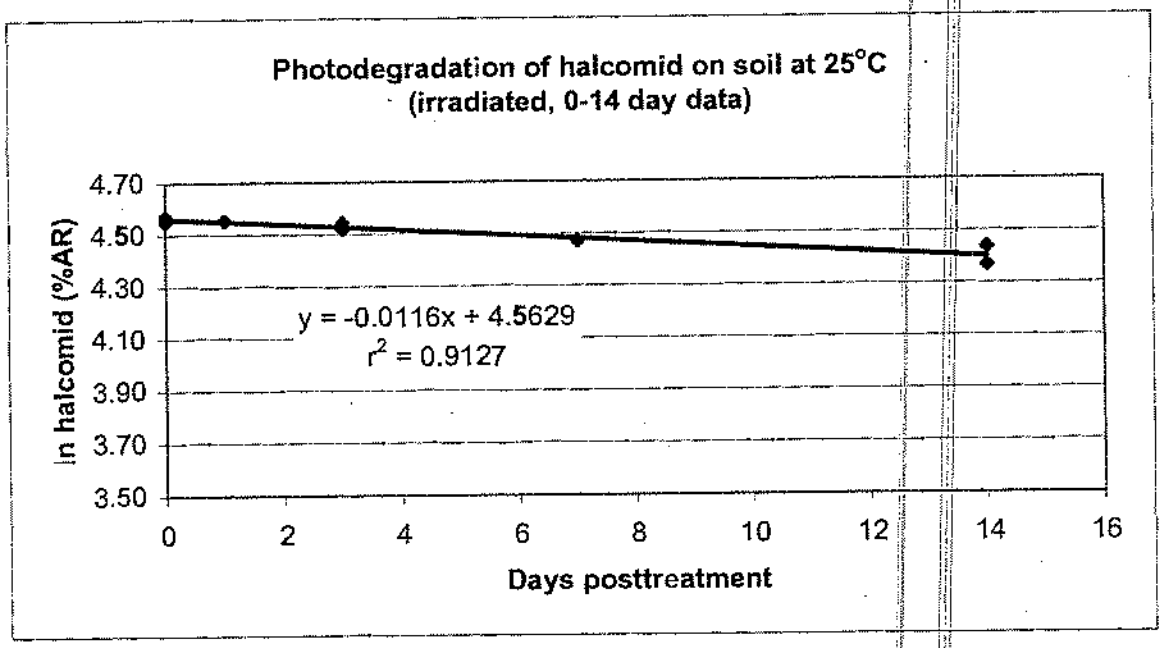
Chemical Name: Halcomid
PC Code: 999999
MRID: 45369734
Guideline No.: 161-3

Half-life: 59.75 days

25°C **Irradiated 0-14 day data**

Days	Halcomid (% AR)	Halcomid (%AR)
0	96.6	4.5706
0	94.7	4.5507
1	95.2	4.5560
3	94.0	4.5433
3	91.8	4.5196
7	87.4	4.4705
14	84.5	4.4368
14	78.8	4.3669

Data obtained from Table 6, p. 49 of the study report.



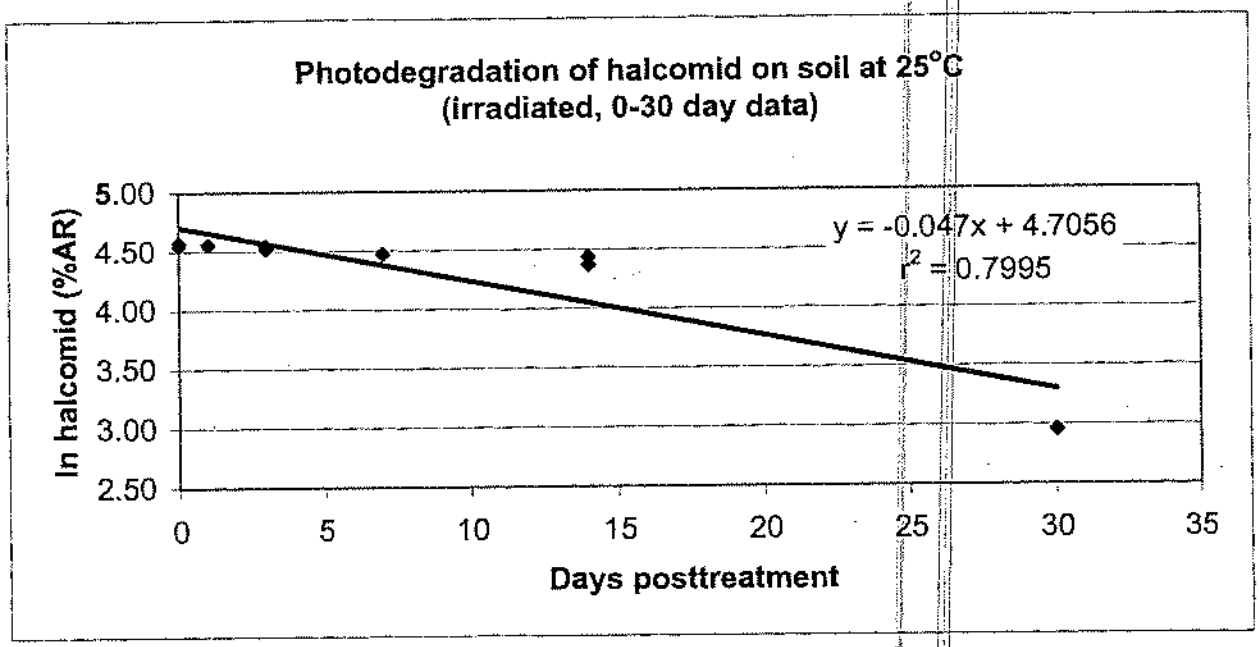
Chemical Name: Halcomid
PC Code: 999999
MRID: 45369734
Guideline No.: 161-3

Half-life: 14.75 days

25°C **Irradiated 0-30 day data**

Days	Halcomid (% AR)	ln Halcomid (%AR)
0	96.6	4.5706
0	94.7	4.5507
1	95.2	4.5560
3	94.0	4.5433
3	91.8	4.5196
7	87.4	4.4705
14	84.5	4.4368
14	78.8	4.3669
30	19.2	2.9549

Data obtained from Table 6, p. 49 of the study report.



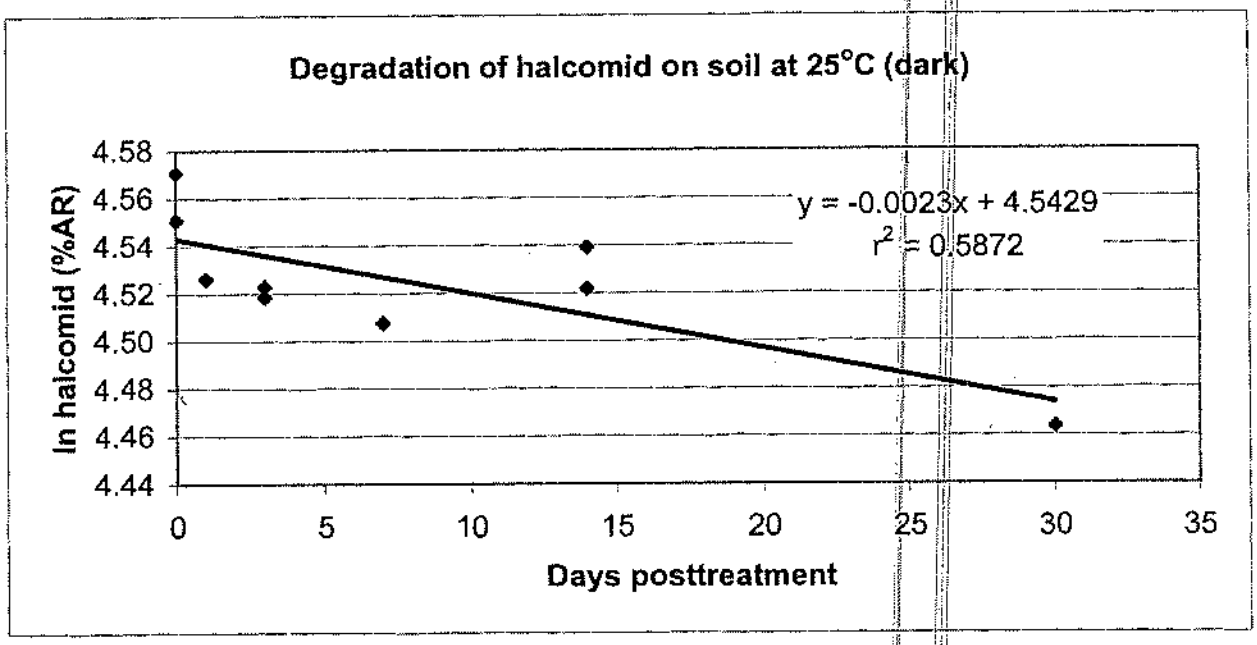
Chemical Name: Halcomid
PC Code: 999999
MRID: 45369734
Guideline No.: 161-3

Half-life: 301.37 days

25°C **Dark**

Days	Halcomid (% AR)	ln Halcomid (%AR)
0	96.6	4.5706
0	94.7	4.5507
1	92.4	4.5261
3	91.7	4.5185
3	92.1	4.5229
7	90.7	4.5076
14	93.6	4.5390
14	92.0	4.5218
30	86.8	4.4636

Data obtained from Table 7, p. 50 of the study report.



Chemical Name: Halcomid
PC Code: 999999
MRID: 45369734
Guideline No.: 161-3

Mass Balance in % of applied radioactivity
Data obtained from Table 4, p. 47 of the study report.

25°C Irradiated

			Bound Residues							
	Days	Extract	Reflux 70C	Non-extract	Total	CO2	Ethyl Gycol	Ch wash	Total %AR	Total %AR
	0	98.6	0.0	2.7	2.7	0.0			101.3	101.3
	0	96.4	0.0	2.5	2.5	0.0			98.9	98.9
Mean		97.5		2.6	2.6				100.1	
SD		1.6		0.1	0.1				1.7	
	1	97.0	1.7	0.3	2.0	0.1	<0.05		99.1	99.1
	3	96.5	2.9	0.5	3.4	0.1	0.1		100.1	100.1
	3	95.3	2.9	0.6	3.5	0.1	0.1		99.0	99.0
Mean		95.9	2.9	0.6	3.5	0.1	0.1		99.6	
SD		0.8	0.0	0.1	0.1	0.0	0.0		0.8	
	7	93.5	3.2	0.7	3.9	0.3	0.1		97.8	97.8
	14	92.7	1.7	0.7	2.4	0.5	0.1		95.7	95.7
	14	88.6	2.0	0.6	2.6	0.5	0.1		91.8	91.8
Mean		90.7	1.9	0.7	2.5	0.5	0.1		93.8	
SD		2.9	0.2	0.1	0.1	0.0	0.0		2.8	
	30	66.8	2.7	3.2	5.9	5.8	0.1	14.7	93.3	93.3
									Mean	97.4
									SD	3.2

Chemical Name: Haicomid
PC Code: 999999
MRID: 45369734
Guideline No.: 161-3

Distribution of Radioactivity in % of applied radioactivity
Data obtained from Table 6, p. 49 of the study report.

25°C **Irradiated**

	Days	Parent D1	Unk D2	Unk D3	Unk D4	Unk D5	Unk D6	Unk D7	WAK 6747 D8	Acid of D8 D9	Unk D10
	0	96.6			2.0						
	0	94.7			1.7						
Mean		95.7			1.9						
SD		1.3			0.2						
	1	95.2			1.8						
	3	94.0			2.5						
	3	91.8		1.4	2.1						
Mean		92.9		1.4	2.3						
SD		1.6			0.3						
	7	87.4	0.9	2.1	3.1						
	14	84.5	2.4	2.3	2.5	1.0					
	14	78.8	2.7	3.2	2.6	1.3					
Mean		81.7	2.6	2.8	2.6	1.2					
SD		4.0	0.2	0.6	0.1	0.2					
	30	19.2	1.2	1.6	1.0	3.9	2.0	2.6	31.5	1.9	1.9

Chemical Name: Halcomid
PC Code: 999999
MRID: 45369734
Guideline No.: 161-3

Mass Balance in % of applied radioactivity
Data obtained from Table 5, p. 48 of the study report.

25°C Dark

			Bound Residues							
	Days	Extract	Reflux 70C	Non-extract	Total	CO2	Ethyl Gycol	Ch wash	Total %AR	Total %AR
	0	98.6	0.0	2.7	2.7	0.0			101.3	101.3
	0	96.4	0.0	2.5	2.5	0.0			98.9	98.9
Mean		97.5		2.6	2.6				100.1	
SD		1.6		0.1	0.1				1.7	
	1	93.6	2.8	0.6	3.4	0.2	<0.05		97.2	97.2
	3	92.6	2.9	0.6	3.5	0.4	<0.05		96.5	96.5
	3	93.3	3.3	0.8	4.1	0.4	<0.05		97.8	97.8
Mean		93.0	3.1	0.7	3.8	0.4			97.2	
SD		0.5	0.3	0.1	0.4	0.0			0.9	
	7	92.2	3.3	0.8	4.1	0.5	<0.05		96.8	96.8
	14	93.6	3.6	1.0	4.6	1.1	<0.05		99.3	99.3
	14	93.9	3.8	1.3	5.1	1.1	<0.05		100.1	100.1
Mean		93.8	3.7	1.2	4.9	1.1			99.7	
SD		0.2	0.1	0.2	0.4	0.0			0.6	
	30	89.4	2.6	1.2	3.8	2.0	<0.05	3.2	98.4	98.4
									Mean	98.5
									SD	1.6

Chemical Name: Halcomid
PC Code: 999999
MRID: 45369734
Guideline No.: 161-3

Distribution of Radioactivity in % of applied radioactivity
Data obtained from Table 7, p. 50 of the study report.

25°C Dark

	Days	Parent D1	Unk D4	WAK 6747 D8
	0	96.6	2.0	
	0	94.7	1.7	
Mean		95.7	1.9	
SD		1.3	0.2	
	1	92.4	1.2	
	3	91.7	0.9	
	3	92.1	1.2	
Mean		91.9	1.1	
SD		0.3	0.2	
	7	90.7	1.5	
	14	93.6	0.0	
	14	92.0	1.9	
Mean		92.8	1.0	
SD		1.1	1.3	
	30	86.8	0.7	1.9

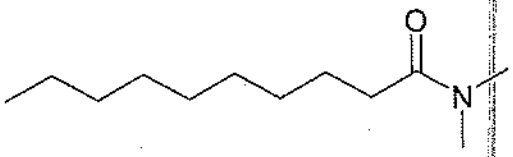
Attachment 2

Structures of Parent and Transformation Products

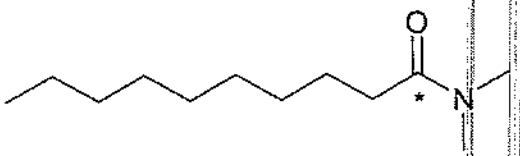
Halcomid

IUPAC name: N,N-Dimethyldecanoic acid amide.
CAS name: Not reported.
CAS No: Not reported.
SMILES string: O=C(CCCCCCCCC)N(C)C

Unlabeled



[1-^{14}C]Halcomid

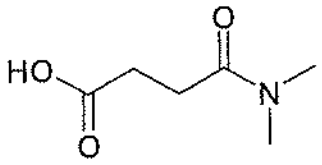


* Position of radiolabel.

Identified Compounds

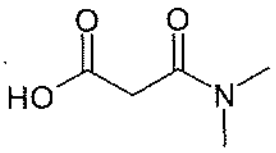
WAK 6747

IUPAC name: Not reported.
CAS name: N,N-dimethylsuccinic acid monoamide.
CAS No: Not reported.



Acid of WAK 7034

IUPAC name: Not reported.
CAS name: N,N-dimethylmalonoic acid monoamide.
CAS No: Not reported.



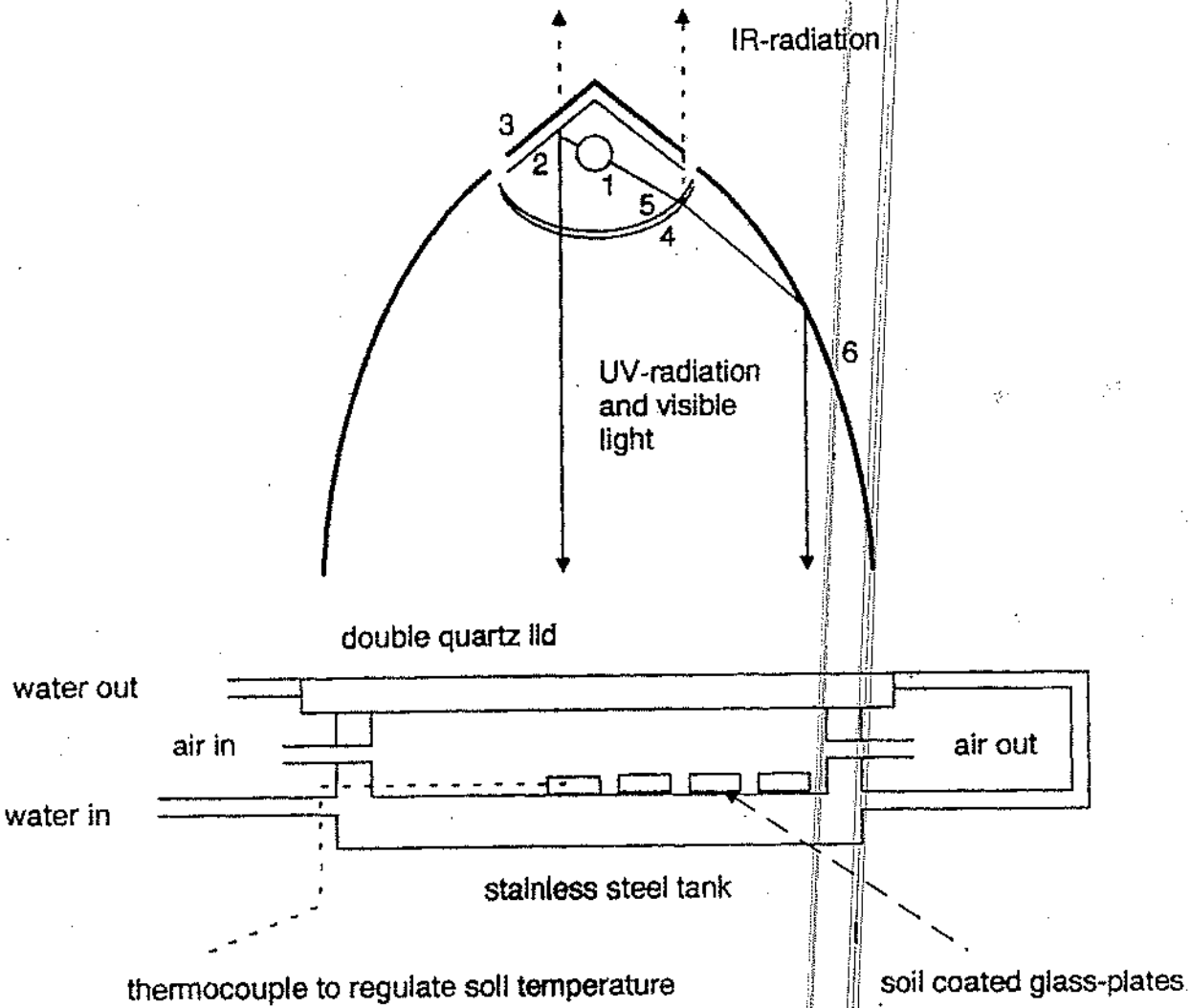
Unidentified Reference Compounds

N,N-Dimethyloctanoic acid amide
Structure not provided.
Decanoic acid
Structure not provided.
Decanedioic acid
Structure not provided.

Attachment 3

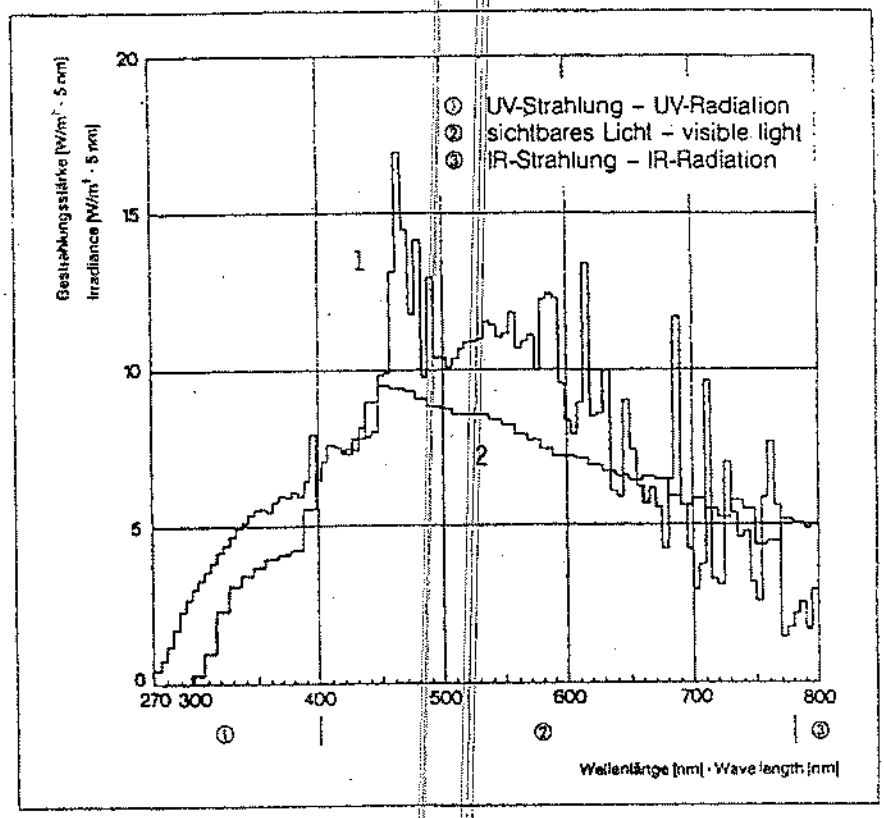
Transformation Pathway Presented by Registrant
Illustration of Test System
Comparison of Artificial Light to Natural Sunlight
Spectral Energy Distributions

Figure 1: Diagram of the Suntest apparatus and the incubation chamber.



1 XENON burner
2 UV mirror
3 Light mirror
4 Quartz glass dish with selective reflecting coating
5 Supplementary filter made of special UV glass
6 Parabolic reflector

Figure 2: Spectral energy distribution (absolute figures) of the Xenon lamp in relationship to the global radiation.

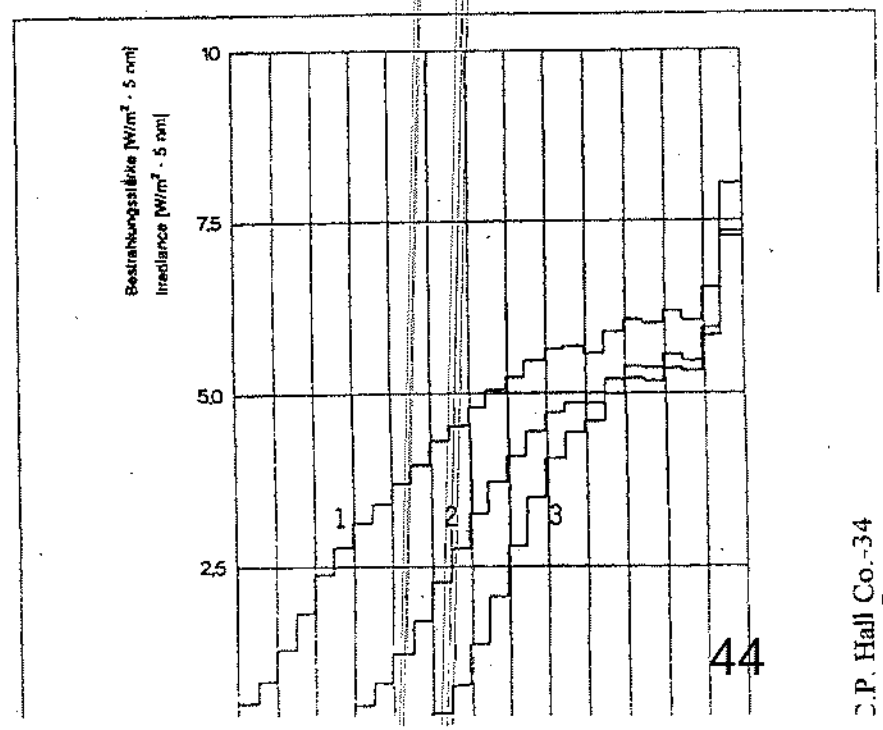


—— SUNTEST-Strahlung ohne zusätzliche UV-Filter
1
—— SUNTEST radiation without additional UV filter

—— Globalstrahlung nach Tageslichtphase D 65
2
—— Global radiation according to daylight D 65

Alle Angaben beziehen sich auf die maximale Bestrahlungsstärke.

All figures refer to the maximum irradiance val.

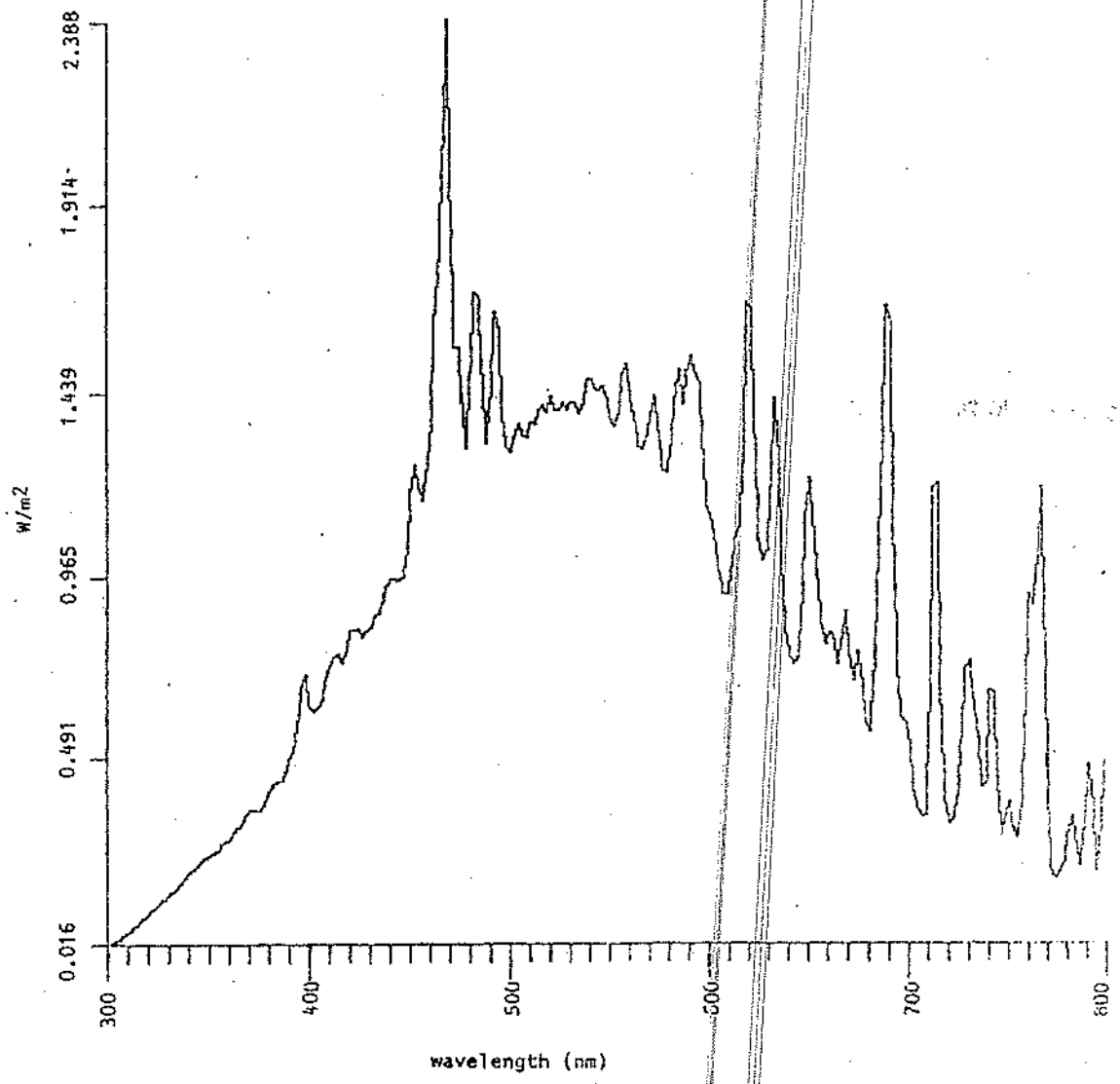


—— ohne Zusatzfilter z. B. für die Prüfung der Kreidungsbeständigkeit
1
—— without additional filters e. g. for testing of chalking

—— mit Zusatzfilter aus UV-Spezialglas z. B. für die Prüfung der Farbbeständigkeit
2
—— with additional filters of special UV filterglass, e. g. for testing of colour change

—— mit Zusatzfilter aus Fensterglas für die Prüfung entsprechend Sonnenlicht hinter Fensterglas
3
—— with additional windowglass filters for test procedures according to simulation of sunlight behind glass.

Figure 3: Spectral energy distribution of the Suntest apparatus before the start of the study (as measured behind the cooled double quartz lid).



RCC PROJECT 370247
N,N-DIMETHYLDECANOIC ACID AMIDE

Figure 4: Spectral energy distribution of the Suntest apparatus at the end of the study (as measured behind the cooled double quartz lid).