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SR - 1,3 Dichloropropene

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Revised Occupational and Residential/Bystander Risk Assessments for Telone

TO: Lisa Nisensen, Chemical Review Manager
Special Review Branch,
Special Review and Reregistration Division (7508W)

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FROM: Christina Scheltema, Chemical Manager
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THROUGH: Michael Metzger, Acting Chief, Risk Characterization and Analysis Branch,
Health Effects Division (7509C)

and Stephanie Irene, Acting Director
Health Effects Division

Attached is the revised occupational and residential/bystander risk assessment for Telone. This risk assessment incorporates risk mitigation measures adopted by DowElanco as part of an agreement reached in negotiations in December 1995. Where possible, quantitative exposure reductions have been factored into the risk estimates. Where scientific uncertainty prohibits quantitative reductions in exposure, a qualitative narrative is provided. This supersedes all previous risk assessment documents. HED has provided revised cancer risk estimates for the major agricultural uses of Telone. The attached risk assessment incorporates comments and input contributed by RCAB, OREB, CBRS, SAB, and TOXII.

Attachments

cc: Lois Rossi
Nancy Zahedi
Jim Stone
Jim Carleton
Karen Whitby
RCAB Chemical File
CASWELL File

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Revised Telone Risk Assessment for Occupational and Residential/Bystander Exposure

HED Telone Team Members: (Members responsible for review of technical accuracy, occupational exposure estimates, issues presented and policies as relevant to this risk assessment.)

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I. EXECUTIVE SUMMARY

HED has performed a revised occupational and residential risk assessment for Telone (1,3-dichloropropene) to incorporate a new Q_1^* value. The inhalation Q_1^* was revised to incorporate the 3/4 scaling factor[1], and cancer risk estimates have been adjusted accordingly. Revised cancer risk estimates have been provided for commodities comprising 90% of all Telone usage, as recommended by the OPP Telone team in the fall of 1994. Occupational and residential/bystander risk estimates were provided for crucifers, peppers, cucurbits, sugar beets, cotton, tobacco, potatoes, sweet potatoes, peanuts, fruit/nut trees and grapevines, onions, tomatoes, carrots, and pineapples. In addition, HED has provided risk estimates for residents/bystanders who spend 16 hours/day at the edge of a 300 foot buffer zone separating occupied structures from treated fields.

Telone was classified as a Group B2 carcinogen by the Cancer Peer Review Committee (CPRC) on December 8, 1989 based on tumor induction in rats and mice by the oral and inhalation routes. HED derived an inhalation Q_1^* of 5.33×10^{-2} $(mg/kg/day)^{-1}$ for Telone, based on the incidence of benign bronchioalveolar adenoma in male mice in a 2-year inhalation study, using the 3/4 interspecies scaling factor and the linearized low dose multistage model (Fisher 1994).

Heritable mutation is another potential hazard endpoint, but supporting evidence is limited. A Data Call In (DCI) will soon be issued for an alkaline elution assay, which detects damage to germ cells in mammals in vivo. Data from this assay are expected by late FY 1997. The results of this assay should reduce uncertainty.

Inhalation is the only significant route of exposure. Occupational and residential/bystander exposure estimates were based on exposure monitoring studies submitted by DowElanco under the conditions of a Data Call In (DCI) and an additional voluntary exposure monitoring study on a minibulk delivery system.

Cancer risk estimates for occupational and residential/bystander exposure to Telone are given in Tables 1, 2, and 3. The excess individual lifetime cancer risk estimates for occupational exposure range from 4.5×10^{-5} to 1.1×10^{-6} for custom operators[2] using typical mitigation measures and from 3.6×10^{-5} to 3.1×10^{-6} for private growers using typical mitigation measures. Cancer risk estimates for residents/bystanders range from 9.7×10^{-6} to 1.0×10^{-6} for individuals living or working 16 hours/day at a fixed distance 125 meters from a treated field, at the edge of the 300 foot buffer zone around occupied structures. This is a conservative estimate for a small population.

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[1] The Q_1^* was revised using a 3/4 scaling factor rather than the 2/3 scaling factor previously used. This reflects a change in science policy (Fenner-Crisp 1994).

[2] custom loaders and applicators

II. BACKGROUND

Telone, or 1,3-dichloropropene, is a highly volatile liquid used as a broad-spectrum preplanting fumigant to control nematodes, insects, and certain bacterial, fungal, and viral diseases on vegetable, fruit and nut, nursery and field crops. Telone was first introduced as a soil fumigant by the Dow Chemical Company in 1955 and subsequently registered in 1966.

Telone is presently registered for nonfood agricultural and domestic outdoor use. No tolerances or exemptions from the requirement of tolerance for residues have been established for food or feed commodities. HED has determined that tolerances are unnecessary because no Telone residues are found in food or feed (Miller 1995). On this basis, dietary risk from Telone is expected to be negligible.

Two commercial formulations are currently available: Telone II and Telone C-17. The active ingredient is a mixture of approximately equal proportions of the cis- and trans-isomers of 1,3-dichloropropene. The Telone II formulation contains 94% 1,3-dichloropropene and 6% inert ingredients. The Telone C-17 formulation contains 77.9% 1,3-dichloropropene 16.5% chloropicrin, and 5.6% inert ingredients. This risk assessment was performed on the active ingredient, 1,3-dichloropropene, henceforth referred to as Telone.

In 1988 alone, 16.5 million lbs of Telone were sold in California, which constituted about one-half of all telone usage (Rabiu and Zavolta 1990). In April 1990, due to high ambient air concentrations measured near densely populated areas in Merced County, California, California Department of Pesticide Regulation (DPR) revoked all permits for Telone usage. From 1990 to 1994, Telone use was suspended from commercial use in California. However, California's DPR has allowed limited re-introduction of Telone, with careful monitoring through DPR's permitting program.

The physical and chemical properties of Telone are listed below:

CAS Number:	542-75-6
Empirical Formula:	$C_3H_4Cl_2$
Physical State:	liquid under pressure, volatile
Molecular Weight:	110.98
Odor:	sweet, pungent, penetrating
Water Solubility:	0.218 g/100 mL for cis isomer 0.232 g/100 mL for trans isomer

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Vapor Pressure:	34.3 mmHg for cis isomer at 25°C 23.0 mmHg for trans isomer at 25°C
Boiling Point:	104°C for cis isomer 112.6°C for trans isomer
Specific Gravity:	1.209 g/mL at 25°C

Telone is applied by injection of the liquid below the soil surface. Because of its high vapor pressure, the liquid then volatilizes and moves rapidly through the soil. Telone may be degraded while in the soil or it may offgass or migrate to groundwater. Occupational and residential/bystander inhalation exposure occurs as a result of Telone offgassing. Inhalation is the primary route of exposure. The rate of Telone offgassing is affected by application method, soil sealing method, soil composition (e.g, amount of clay and organic matter), and soil moisture and temperature.

Telone is applied to soil by two methods: row and broadcast. With both methods, Telone is injected 12-16 inches below the final sealed soil surface. The broadcast method uses one chisel, nobel (sweep) plow or plow-sole application equipment with one or more fumigant outlets. The broadcast method requires the formation of a raised bed after the application. The row method consists of either one or two chisels per plant row to treat a band of soil where the crop is to be planted. The row method involves forming beds at the time of application so that the fumigant is placed at least 12 inches from the nearest soil/air interface.

Telone loading practices vary. Bulk loading is the predominant practice in some regions, including the Pacific Northwest, with growers purchasing Telone from bulk transfer stations. Custom operators in the Pacific Northwest transport Telone throughout the region in tanker trucks. Drum loading is also used, but will be phased out by December 31, 1996. Drums will be replaced by a new minibulk loading system in some areas. This system involves portable 1000-gal "traveler" cylinders with dry disconnects.

DowElanco has agreed to place additional mitigation measures on their label following negotiations with the Office of Pesticide Programs in December, 1995. These mitigation measures have been incorporated into this risk assessment.

III. HAZARD IDENTIFICATION/DOSE-RESPONSE ASSESSMENT

A. Carcinogenicity

The HED Carcinogenicity Peer Review Committee (CPRC) met on December 8, 1989 to evaluate the carcinogenic potential of Telone. The Committee classified Telone as a Group B2, probable human carcinogen, based on the results of chronic inhalation and oral studies in rats and mice (Dearfield 1989). The Telone II formulation was tested for carcinogenicity by both Dow Chemical (inhalation studies) and the National Toxicology Program (NTP, oral studies).

1. Inhalation Studies

DowElanco tested the carcinogenic potential of Telone II in mice and rats following chronic inhalation exposure. The test compound contained 92% 1,3-dichloropropene in a stabilizer of [redacted]

a. Mouse study

Male and female B6C3F1 mice received Telone II via inhalation in live-in chambers (Levy 1988, MRID # 403123-00). Groups of 50 animals/sex/dose received 0, 5, 20, or 60 ppm Telone II (0, 6.88, 27.51, or 82.54 mg/kg/day, respectively) 6 hours/day, 5 days/week for two years. An additional 10 animals/sex/dose were sacrificed at 6 and 12 months.

A statistically significant increase in the incidence of bronchioalveolar adenoma (a benign lung tumor) was found in male mice at 60 ppm, the highest dose tested, by pairwise comparison with controls. A significant positive-trend was also found. The incidence of these lung tumors was also outside the historical range. Male mice at 20 ppm showed a significant difference in the incidence of lacrimal gland cystadenomas by pairwise comparison with controls. Female mice treated at 5 ppm showed a significant difference in the incidence of mesenteric lymph node lymphosarcoma by pairwise comparison with controls.

Hypertrophy and/or hyperplasia of the urinary bladder epithelium, nasal mucosal epithelium, and nonglandular stomach were noted. The CPRC concluded that higher dose levels could have been used in this study based on the lack of severity of decreased body weight gain and non-neoplastic histopathology (Dearfield 1989). In addition, the highest dose selected was not substantiated by a 90-day subchronic study.

The CPRC concluded that the bronchioalveolar adenoma seen in high dose males was the only tumor of concern. This tumor was also seen in female mice in an oral carcinogenicity study described below. The CPRC recommended dose response quantification for the inhalation route based on the incidence of this tumor.

b. Rat Study

Male and female F344 rats received Telone II via inhalation in live-in chambers (Levy 1987, MRID # 403122-01). Groups of 50 animals/sex/dose received 0, 5, 20, or 60 ppm Telone II (0, 2.68, 10.73, or 32.20 mg/kg/day, respectively) 6 hours/day, 5 days/week for two years. An additional 10 animals/sex/dose were sacrificed at 6 and 12 months.

No evidence of carcinogenicity was noted in F344 rats following chronic inhalation

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exposure. Non-neoplastic lesions were limited to papilloma (1 control female) and focal nonglandular mucosa hyperplasia (1 male at 60 ppm and 2 females at 5 ppm). The CPRC considered these non-neoplastic lesions confirmatory of tumors at the same sites in the rat oral study described below.

No compound related effects on mortality, clinical signs, organ weights, urinalysis, or hematology were noted. Slight decreases in body weight gain were noted in males and females at 60 ppm during the first year of the study only. Histopathological lesions of the olfactory region of the nasal cavity were noted in males and females at 60 ppm.

The CPRC concluded that the dosing in the rat study was inadequate to detect carcinogenic potential. In addition, the dose selection was not substantiated by a 90-day subchronic study.

2. Oral Studies

The oral carcinogenicity studies for Telone were evaluated by the CPRC on September 5, 1985 (Quest 1985). The conclusions of this CPRC did not change significantly with the subsequent 1989 Carcinogenicity Peer Review.

NTP tested the chronic toxicity and carcinogenic potential of Telone II in F344 rats or B6C3F1 mice (NTP, 1985). The test compound contained 92% 1,3-dichloropropene (mixed isomers), 2% 1,2-dichloropropane (impurity), 1% epichlorohydrin (stabilizer), and 5% chlorinated propenes and hexenes.

a. Rat Study

Male and female F344 rats received Telone II by corn oil gavage at 0, 25, or 50 mg/kg/day, 3 days/week for 24 months. A total of 77 rats/sex were used for each dose group; 52 animals/sex/group were dosed for 24 months in the main carcinogenicity study; an additional 5 animals/sex/group were sacrificed after 9, 16, 21, 24, and 27 months of dosing, respectively.

Statistically significant increases in the incidence of the following tumors were observed at 50 mg/kg/day, the highest dose tested by pairwise comparison with controls:

- forestomach squamous cell papillomas in males and females; combined forestomach squamous cell papillomas and carcinomas in males;

- liver neoplastic nodules in males and combined neoplastic nodules and hepatocellular carcinomas in males.

The increased incidence of forestomach tumors was accompanied by a statistically significant positive trend for forestomach basal cell hyperplasia in male and female rats at doses of 25 and 50 mg/kg/day. There were also positive trends for other tumors in rats (mammary gland adenomas or fibromas and thyroid gland follicular cell adenomas or carcinomas in females, adrenal gland pheochromocytomas in males). The highest dose tested (50 mg/kg/day) appeared to be adequate for carcinogenicity testing. No increased mortality occurred in treated animals.

The 1985 CPRC considered the evidence that the epichlorohydrin stabilizer might have contributed to the incidence of forestomach tumors in the rat study (Quest 1985). The CPRC concluded that the tumors could not be solely attributed to epichlorohydrin because tumors were seen at sites other than the forestomach (i.e., liver, mammary gland, and thyroid) and the dose of epichlorohydrin was far below that associated with forestomach tumors in gavage and drinking water carcinogenicity studies on epichlorohydrin.

b. Mouse Study

Male and female B6C3F1 mice received Telone II by corn oil gavage at doses of 0, 50 or 100 mg/kg, 3 days/week for a total of 104 weeks. Groups of 50 mice/sex/dose were tested; there was no interim sacrifice group in the mouse study. The results of the study were confounded by an excessive mortality in control males from myocarditis.

Forestomach, urinary bladder, and lung tumors were observed. Increased incidences of forestomach squamous cell papillomas were noted in males and females at 50 and 100 mg/kg/day dose levels; increased incidences of combined forestomach papillomas and carcinomas were noted in females at 100 mg/kg/day. This was accompanied by an increased incidence of stomach epithelial cell hyperplasia in males and females at the 100 mg/kg/day dose. Increases in urinary bladder transitional cell carcinomas occurred in males at 100 mg/kg/day and in females at 50 and 100 mg/kg/day; tumor incidence was statistically significant and dose related in females. The urinary bladder transitional cell carcinoma was accompanied by a positive trend for bladder hyperplasia in males and females at the 50 and 100 mg/kg/day doses. An increased incidence in lung adenomas in males and females was observed at 50 and 100 mg/kg/day. A positive trend in the incidence of adenomas and combined adenomas and carcinomas was observed in females, with a statistically significant tumor incidence at 100 mg/kg/day.

Several deficiencies were noted in the mouse study, including excessive mortality in control males and inadequate randomization procedures at study initiation (Quest 1985). The high dose appears to have been excessive. HED considers the mouse oral carcinogenicity study to be supplementary.

3. Mutagenicity

Telone has been tested for mutagenic activity in several test systems. Telone produced gene mutation in bacterial and mammalian test systems <u>in vitro</u> but did not produce structural chromosomal aberrations in mammalian test systems. Telone is also a germ cell mutagen in Drosophila in vivo.

a. FIFRA Mutagenicity Data

Telone tested positive for point mutations in the Ames assay in Salmonella strains G46, TA100, and TA1535 with and without activation and in strains TA1537 and TA1538 without activation; negative results were seen in E. coli. Telone was positive for DNA damage in the B. subtilis rec assay. Telone produced a very slight increase in gene mutation (2X background) in Chinese hamster ovary (CHO) cells in vitro, with and without activation but this effect was not reproducible. Telone was negative for clastogenesis and aneugenesis in the mouse micronucleus assay (gavage administration). Mortality was noted at high doses in the micronucleus study, so dosing was considered adequate. Telone did not induce unscheduled DNA synthesis in primary rat hepatocytes in vitro.

b. NTP Mutagenicity Studies

NTP sponsored several mutagenicity studies on Telone. NTP data show Telone to be positive in Salmonella with and without activation, positive in the mouse lymphoma assay without activation, and positive in the sister chromatid exchange (SCE) assay in V79 cells with and without activation. Telone was also positive in the sex-linked recessive lethal assay in Drosophila (dietary administration).

c. Mutagenicity Data Gaps

To confirm the results of the Drosophila sex-linked recessive lethal in a mammalian species in vivo, a Data Call In (DCI) will soon be issued for an alkaline elution assay in testicular cells (following inhalation administration). Positive results in this test system would trigger additional testing (e.g., mouse specific locus assay) to determine whether Telone produces heritable mutations in vivo.

4. Weight of Evidence for Carcinogenicity

The CPRC considered the following weight of evidence for a determination of Telone's carcinogenic potential (Dearfield 1989). Telone II was associated with the following effects in a 2-year oral (gavage) bioassay in F344 rats: an increase in forestomach squamous papillomas and basal cell hyperplasia (both sexes at the highest dose), combined papillomas and carcinomas in males, liver neoplastic nodules in high dose males, and positive trends for other tumor types, including mammalian cell adenomas or fibromas and thyroid gland follicular cell adenomas or carcinomas in females, and adrenal gland pheochromocytomas in males. Telone II was associated with the following effects in an oral bioassay in B6C3F1 mice: increased forestomach squamous cell papillomas and carcinomas (both sexes, both doses), combined papillomas and carcinomas in high dose females, urinary bladder transitional cell carcinomas in (high dose males, females at both doses), a positive trend in urinary bladder hyperplasia (both sexes), lung adenoma (both sexes, both doses), and combined lung adenomas and carcinomas (males, both doses).

Telone II was associated with increased bronchioalveolar adenomas (benign) in high dose males in an inhalation bioassay in B6C3F1 mice; hypertrophy and/or hyperplasia of the urinary bladder epithelium, nasal mucosal epithelium and nonglandular stomach were also noted. **Although the lung tumors noted in the mouse inhalation study were benign, tumor induction was dose dependent, tumor incidence was outside the range of historical controls, and the tumor type was also seen in the mouse oral bioassay.**

Based on these considerations, the CPRC considered the lung tumors to be biologically significant. Non-neoplastic urinary bladder and nonglandular stomach lesions seen in the mouse and rat inhalation studies provided additional evidence for the carcinogenicity of Telone II. These sites were associated with increased tumor incidence in the oral studies.

Telone II was not associated with any tumors in the inhalation bioassay in F344 rats; however, the CPRC determined that the dose levels in this study were not high enough to fully assess carcinogenic potential.

The positive results in bacterial, Drosophila, and mammalian cell mutagenicity studies also contribute to the weight of evidence for carcinogenicity. Further, Telone is structurally similar to vinyl chloride, which produces lung tumors following inhalation exposure, and epichlorohydrin, which produces forestomach tumors following oral administration and nasal tumors following inhalation exposure.

5. Human Data

Reports of hematological malignancies following accidental exposure to Telone were published in the literature subsequent to the CPRC meeting on Telone (Markovitz and Crosby 1994 and Hernandez et al. 1994). These reports were reviewed by HED in November 1994 (Allen 1994). The first report (Markovitz and Crosby 1994) describes two firemen exposed to Telone during cleanup of a tank car accident and one farmer who was sprayed in the face when a pressure injection hose malfunctioned. All 3 exposed individuals developed hematological malignancies within 7 years of exposure. HED concluded that this represents an important group of sentinel cases, the first published link between a documented acute pesticide poisoning and development of aggressive, fatal hematological malignancies. The second report (Hernandez et al. 1994) describes the outcome of a worker who accidentally drank a solution containing Telone and died 40 hours later, after developing respiratory and gastrointestinal distress and hematological, hepatic, and renal failure. HED concluded that this second report supports concern for Telone toxicity to the human hematologic system.

B. Cancer Dose-Response Quantification

The Carcinogenicity Peer Review Committee determined that dose-response

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quantification should be performed for both the inhalation and oral routes, using the linear low-dose extrapolation model. An oral Q_1^* of 1.75 X 10^{-1} (mg/kg/day)$^{-1}$ in human equivalents was calculated based on the incidence of forestomach or liver or adrenal or thyroid tumors in male rats, the most sensitive gender and species, using the 2/3 interspecies scaling factor (Fisher 1986)[3]. An inhalation Q_1^* of 5.33 X 10^{-2} (mg/kg/day)$^{-1}$ in human equivalents was calculated based on the incidence of bronchioalveolar adenomas in male mice, using the 3/4 interspecies scaling factor and the linearized low dose multistage model (Fisher 1994). This inhalation Q_1^* of 5.33 X 10^{-2} supersedes the earlier value established in 1990 (9.66 X 10-2 (mg/kg/day)$^{-1}$, 2/3 interspecies scaling factor) (Fisher 1990).

IV. EXPOSURE ASSESSMENT

The Occupational and Residential Exposure Branch (OREB) estimated exposures for loaders, applicators, and residents/bystanders from the major uses of Telone. The exposure assessment was limited to the inhalation route; dermal exposure is expected to be negligible.

Exposure estimates were based on air monitoring data submitted by DowElanco in response to the 1993 Data Call In and an additional voluntary air monitoring study submitted during the 1995 negotiations. The exposure monitoring data were limited to a few major Telone uses; these monitoring data were extrapolated to derive exposure estimates for additional crops that comprised high use sites for Telone (Mehta 1995 personal communication, Carleton 1996).

OREB performed four exposure assessments for Telone: residential exposure assessment (Mehta 1994a), worker exposure assessment (Mehta 1994b), revised worker and residential exposure (and risk) assessment (Carleton 1995a and b), and updated exposure and risk estimates reflecting new study data (Carleton 1996). These assessments provide a comprehensive overview of the worker and residential exposure studies submitted in response to the Data Call In (DCI) and the subsequent voluntary worker monitoring study using minibulk "traveler" cylinders. The conclusions of these assessments are summarized below.

A. Factors Influencing Telone Exposure

Local soil conditions, such as soil type, moisture, organic content, and soil temperature all influence the rate of Telone offgassing and subsequent exposure to workers or residents. Telone application methods, including soil sealing, injection depth, and placement of injection shanks influence Telone offgassing. Local meteorological conditions, such as prevailing wind, also influence air concentrations and exposure potential. Application rate may also influence Telone offgassing, although a quantitative relationship

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[3] The oral Q_1^* was derived using the 2/3 scaling factor to extrapolate from animals to humans. In 1994, HED adopted the policy of using the 3/4 scaling factor. Because the oral route of exposure is not of concern, HED has not yet revised the oral Q_1^* using the 3/4 scaling factor.

between application rate and air concentration has not been established. In addition, Telone exposure may vary with time after application. Peak Telone offgassing generally occurs over the first 72 hours following Telone application, although detectable vapors are still present 14 days following application. [4] Telone exposure also varies with distance from treated fields. Telone air concentrations measured 125 meters from treated fields were 45 to 72% lower than air concentrations measured 5 meters from treated fields (Carleton 1996).

B. Exposure Monitoring Studies

DowElanco performed exposure monitoring studies for both workers and area residents. A number of exposure studies were submitted to fulfill OPP or California DPR data requirements. Studies used for the HED Worker and Resident/Bystander Risk Assessments are summarized below. Most of these studies are from the 1993 Data Call In. An additional voluntary worker study on minibulk "travelers" was submitted by DowElanco during the 1995 negotiations.

1. Worker Monitoring Studies

Worker monitoring studies involved Telone loading or application using typical methods with and without standard mitigation practices and monitoring of the workers' breathing zone (Mehta 1994b). The Moses Lake, WA and Buckeye, AZ studies collected both 4-hour nominal samples and task-specific short-term (5-83 minute) samples for loaders and applicators (Carleton 1995b, personal communication). The 4-hour samples provided inherently time-weighted average air concentrations over a major fraction of the work day while the short term air samples reflected air concentrations associated only with high-contact activities (e.g., actual loading events). The 4-hour loader samples included the loading events and time between events. The Ainger, NC study collected only task-specific short-term samples (7-25 minute samples for loaders, 60-240 minutes for applicators). The Ainger, NC study did not include measurement of 4-hour time-weighted air concentrations (Carleton 1996a).

Worker re-entry studies involved workers performing various tasks within 4 days of Telone application; sampling duration was 2-4 hours. OREB determined that the limited scope of the re-entry studies precluded using the results to draw general conclusions about re-entry exposures (Carleton 1995a). Worker monitoring studies are described below.

- **Moses Lake, WA Worker Study**. October and November, 1992. Telone II applied at the maximum application rate of 25 gal/acre (252.5 lbs ai/acre) on a field used for potatoes; soil type was sandy loam. Bulk loading was used, with dry disconnects, which are common practice in the region. Application was by the broadcast method.

[4] In two of three residential exposure studies, peak Telone air concentrations occurred within 72 hours of application.

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- **Buckeye, AZ Worker Study.** March 3-10, 1993. Telone II was applied by the row method at the maximum rate of 12 gal/acre (121.2 lbs ai/acre) to a field used to grow cotton; soil type was loamy sand. Bulk loading was used, with and without dry disconnects.

- **Ainger, NC Worker Study.** April 3-5, 1995. Telone C-17 was applied by the row method at a rate of ~ 10 gal/acre (82 lbs ai/acre) to a field used to grow tobacco. Soil type was not specified. This study utilized new Telone minibulk delivery system, DowElanco's portable 1000-gallon "traveler" cylinders, which utilize dry disconnects.

DowElanco submitted additional worker monitoring studies conducted in Buckeye, AZ and Hookerton, NC as part of the 1993 DCI. These studies used drum loading systems, which will be phased out by the end of 1996. Therefore, these studies were not used to estimate exposure.

Biological exposure monitoring was also conducted on both sedentary human volunteers (controlled study) and on workers performing typical tasks. Urinalysis was used to detect the major Telone metabolites (Levy 1993, McMahon 1993). These studies are described in detail in the worker exposure assessment for Telone (Mehta 1994b). The biological monitoring data were not used in this HED risk assessment. An accurate correlation between urinary metabolite excretion and the air monitoring data could not be made to estimate absorbed dose (McMahon 1993). The biomonitoring data showed Telone absorption in the range of 72-82%; these absorption estimates were determined to be minimum values after comparison with field trial data. Absorption via the inhalation route was assumed to be 100% for the purposes of this risk assessment.

2. Resident/Bystander Monitoring Studies

Residential/bystander monitoring studies involved air sampling for 14 days at various stations 5, 25, 125, 500 and 800 meters[5] from a Telone treated field. Prior to the initiation of the treatment, baseline air samples were collected at sampling stations located 500 meters from the treatment sites. The applications were conducted utilizing standard cultural practices and equipment. Fields that were selected and treated were isolated from all other known Telone handling activities. Air sampling was conducted in all four compass directions. OREB analyzed data for samples taken downwind from treated fields as well as for pooled data from all four directions (to account for shifts in prevailing wind direction over time). Air sampling was conducted around the clock to account for day and night exposures. Greater Telone ambient air concentrations and volatilization rates were found at night (Mehta 1994a). However, only the 24-hour time-weighted average air concentrations were used to estimate residential/bystander exposures due to a lack of individual time activity data on time spent in and around the house at day and night. Residential/bystander

[5] the AZ site had additional sampling stations at 1200 and 1600 meters from the treated field

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monitoring studies are described below.

- **Phase 1. Moses Lake, WA.** October 26 to November 9, 1992. Air monitoring was conducted at 20 monitoring locations surrounding a 20 acre plot treated with Telone II using the broadcast method at the maximum rate of 25 gal/acre (252.5 lbs ai/acre). Prior to the initiation of the treatment, baseline air samples were collected at sampling stations located 500 meters from the treatment site. The 800 meter south samples could not be collected because a cattle stockyard was located to the south of the treated field. The soil type was characterized as loamy sand.

- **Phase 2. Harquahala Valley, AZ.** February 16 to March 2, 1993. Telone II was applied using the row method at a rate of 12 gal/acre (121.2 lbs ai/acre), imitating an application for a melon field. Air monitoring was conducted at 28 monitoring locations surrounding the 20 acre plot treated with Telone II. The soil type was characterized as a sandy loam.

- **Phase 3. Hookerton, North Carolina.** December 7-21, 1992. Air monitoring was conducted at 20 monitoring locations surrounding a 12 acre plot that had been treated with Telone C-17. Telone C-17 was applied using the broadcast method at a maximum label rate of 20 gal/acre (164 lbs ai/acre) for tobacco. The soil type was characterized as a sandy loam.

C. Exposure Mitigation Measures

During the December, 1995 negotiations, DowElanco agreed to amend Telone product labels to include additional mitigation measures and to revise the Telone product stewardship information in an effort to reduce exposure to Telone products. Specific mitigation measures for workers and area residents are described below.

1. Workers

The new Telone labels will include the following mitigation measures for workers: respiratory protection for all workers handling Telone, an increased re-entry interval of 120 hours (previously 72 hours), reduced application rates, increased injection depth, and soil sealing measures (Rossi 1996). OREB has analyzed the impact of these mitigation measures on worker exposure (Carleton 1996a). The quantitative and qualitative impact of these mitigation measures is described below.

Respiratory Protection. Workers handling Telone are required to wear a NIOSH 23C respirator with an organic vapor cartridge or approved pesticide prefilter. This respirator requirement is expected to reduce exposures by a factor of 90% if used correctly. Therefore, all occupational exposure estimates have been adjusted with a protection factor of 0.10. An exception to the respirator requirement will be made for applicators using charcoal filtered enclosed cabs when language for such cabs is accepted by the Agency and incorporated into Telone labels. There are many issues, including fit, associated with respirator use. However, DowElanco has included strong language on Telone product labels requiring fit testing, training, and examination by a qualified medical practitioner to conform with OSHA requirements.

Re-entry Interval. The increased re-entry interval (REI) of 120 hours is expected to have some protective effect for re-entry workers, although this effect cannot be quantified with available exposure monitoring data. The resident/bystander exposure monitoring studies measured daily Telone air concentrations over 14 days following application. Two of the three resident/bystander monitoring studies showed maximum air concentrations within ~ 3 days following application; detectable vapors were present 14 days following treatment. The third study showed more constant air concentrations over the 14 days following application. These data suggest that long-term exposures to re-entry workers may be reduced by the increased REI, while short-term exposures may not always be affected.

Reduced Maximum Application Rates. Some exposure reduction should result from decreased application rates, although this cannot be quantified with the available data. No relationship has been established between Telone application rate and resulting Telone air concentrations. Also, DowElanco has stated that most Telone handlers use less than the maximum application rate and so it is unclear what effect reduced rates will actually have on the amount of Telone that is handled.

New maximum application rates for the active ingredient 1,3-dichloropropene are specified as follows on the product labels:

- 25 gal/acre for vegetable crops (from 36 gal/acre)
- 18 gal/acre for field crops (from 36 gal/acre)
- 35 gal/acre for fruit and nut crops (from 102 gal/acre)
- 55 gal/acre for nursery crops (ornamentals) (from 102 gal/acre)

Actual use rates for Telone II and Telone C-17 will vary slightly because the two formulations differ in the percentage of 1,3-dichloropropene they contain.

Increased injection depth, soil sealing, and other measures. DowElanco has agreed to increase the required minimum injection depth from 10 to 12 inches below the soil-air interface and the recommended minimum injection depth from 12 to 14 inches. DowElanco will make recommendations for the number, kind, and placement of injection shanks to effectively increase the distance from the point of injection to the soil-air interface for both row and broadcast treatment. DowElanco will also require soil sealing and recommend preferred moisture and temperature parameters prior to and/or during application to limit

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Telone off gassing. Because all of these measures are designed to retain Telone in the soil, they are likely to reduce overall air emissions of Telone and thereby reduce exposures. However, there are no data to quantify the efficacy of any of these measures in reducing overall exposure.

2. Residents/Bystanders

The new Telone labels have one specific provision to mitigate risk to area residents and bystanders: dry buffer zones within 300 feet of an occupied structure. The implementation of this buffer zone should reduce exposure to the resident/bystander population at highest risk: people living near treated fields. All three resident/bystander monitoring studies showed that average Telone air concentrations declined with increasing distance from treated fields. (Air concentrations 125 meters from treated fileds were 45 to 72% lower than those 5 meters from treated fields). Other measures, including use of the "traveller" minibulk loading system, reduced application rates, increased injection depth, soil sealing, and soil moisture requirements may also reduce exposure to residents and bystanders, although exposure reduction cannot be quantified (Carleton 1996a). Exposure to residents and bystanders will also be influenced by local environmental conditions (e.g., soil type, meteorological conditions, etc.).

D. Exposure Estimates.

OREB provided exposure estimates for workers (growers, custom loaders and applicators) and residents/bystanders based on Telone air concentrations measured in the monitoring studies described above. Exposure estimates for growers were based on a time-weighted average air concentration, assuming 0.5 to 1.5 h/day loading activity and 5-10 h/day applying Telone. Exposure estimates for both growers and custom operators were extrapolated from the worker monitoring study with a time duration most relevant to the occupational scenario.

Occupational exposure estimates assume the use of personal protective equipment (PPE) specified on the **proposed** product label (Carleton 1996a). For both Telone C-17 and Telone II, the proposed label specifies that a NIOSH 23C or 14G respirator with a pesticide prefilter or canister approved for pesticides must be worn by all Telone handlers except those using charcoal filtered enclosed cabs. NIOSH assigns a protection factor of 90% to these respirators; i.e., exposure is reduced by an order of magnitude. HED has applied this protection factor of 0.10 to exposure estimates for all workers using Telone (Carleton 1996a and b). Occupational exposure estimates were also adjusted using protection factor of 0.64 for dry disconnects and 0.19 for spill control, where appropriate. Exposure estimates for custom loaders were not adjusted for use of dry disconnects because of data anomalies which suggested increased exposure with use of this specific mitigation measure (Carleton 1995a). Exposure estimates based on the new Ainger, NC "traveler" worker monitoring data were not adjusted for dry disconnects or spill control because these mitigation measures were used in the study.

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To provide crop-specific exposure estimates, HED extrapolated from the exposure monitoring studies described above to the major crops using Telone (Mehta 1995, personal communication). In this extrapolation, HED attempted to match application rate and/or method of loading or application when extrapolating from the monitoring studies to other crops. HED determined that such extrapolation was appropriate because Telone is used as a pre-planting fumigant; volatilization is not dependent on type of foliage or other crop-specific characteristics (Mehta 1995, personal communication). Further, although different application rates of Telone are used for different crops, there are no data to suggest a linear relationship between Telone air concentration and application rate (Knott 1995, personal communication).

For crops grown in more than one state, HED used usage data on exposure duration for the state with the highest Telone usage (Carleton 1995a, 1996a, Michel 1995). This provides a realistic estimate of potential lifetime exposure for cancer risk assessment.

Exposure estimates for residents/bystanders were based on pooled data to account for random shifts in the prevailing wind direction. For residents/bystanders, HED also assumed 16 hours/day spent in and around the house. HED assumed Telone air concentrations to be the same indoors and outdoors, in the absence of indoor air monitoring data. Exposure estimates for residents/bystanders are provided for individuals who remain at a fixed distance from a treated field (Table 3).

The lifetime average daily exposure (LADE) of Telone was estimated for workers and residents/bystanders for exposure related to Telone application to all major crops. The LADE was calculated according to the following formula:

$$\text{LADE (mg/kg/day)} = \frac{(\text{air concentration, } \mu g/m^3)(1 mg/1000\ \mu g)(\text{ventilation rate, } m^3/hr)(hr/day)(days/yr)(1\ yr/365\ days)(yrs\ exposed/70\ yrs)}{70\ kg\ body\ wt}$$

The LADE for workers was adjusted using appropriate protection factors for various mitigation measures, as appropriate. The following protection factors were used: 0.10 for respirators (all scenarios), 0.64 for dry disconnects (loading, except for custom loaders and grower scenarios using Ainger, NC data), and 0.19 for spill control (application except for scenarios using Ainger, NC traveler data).

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HED made the following assumptions for workers and residents/ bystanders:

	Workers	Residents/Bystanders
Ventilation rate	1.74 m^3/h[6]	0.81 m^3/h
Lifetime Exposure	30 yrs grower 20 yrs custom	30 yrs
Average Lifetime	70 yrs	70yrs
Exposure Duration	crop specific	16 h/day
Exposure Frequency	crop specific	15 days/event, 1-2 events/yr

Many of the exposure parameters listed above use standard Agency default assumptions. The career length of 30 years for growers and 20 years for custom operators is a departure from the 40 year career span provided in the Agency's Exposure Factors handbook. The Biological and Economic Analysis Division (BEAD) has researched this issue and determined that 30 years is a reasonable high-end estimate for the number of years a grower might handle Telone, and 20 years is reasonable for a custom operator (Zavolta and Michell, 1996). The lifetime exposure duration of 30 years for residents/bystanders is a departure from the default assumption of 9 years provided in the Agency's Exposure factors handbook; individuals in farming communities are expected to change residences less frequently.

Exposure estimates for growers, custom loaders and applicators, and residents/bystanders are given in Tables 1, 2, and 3, attached.

IV. RISK CHARACTERIZATION

HED estimated cancer risk to growers, custom loaders/applicators, and residents/bystanders exposed to Telone. Exposures via the dermal route were assumed to be negligible due to Telone's high volatility. Therefore, exposures and cancer risks to custom operators, private growers, and residents/bystanders were estimated only for inhalation exposure. Inhalation carcinogenicity data were available and deemed appropriate for quantitative risk assessment. Therefore, route to route extrapolation was not necessary.

[6] Ventilation rate reflects light work, as per the Agency's Exposure Assessment Guidelines.

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A. Cancer Risk Estimates

1. Linearized Low-Dose Extrapolation Model (Q_1^*)

HED determined that it is appropriate to calculate cancer risk estimates for Telone using a Q_1^* derived from the linearized low dose extrapolation model. The Q_1^* used in this assessment was based on the incidence of bronchioalveolar adenomas in males in a mouse inhalation carcinogenicity study.

Estimates of excess individual lifetime cancer risk for custom operators, growers, and area residents/bystanders are given in Tables 1, 2, and 3. Cancer risk estimates were calculated using the following formula:

Extra cancer risk = Q_1^* X LADE

where $Q_1^* = 5.3 \times 10^{-2}$ (mg/kg/day)$^{-1}$

$$\text{and LADE} = \frac{\text{exposure (mg/kg/yr)}}{365 \text{ days/yr}} \times \frac{20 \text{ or } 30 \text{ yrs}}{70 \text{ yrs}}$$

Excess individual lifetime cancer risk estimates presented here reflect the incorporation of new information, changes in a few underlying assumptions, and incorporation of additional mitigation measures into the pending Telone label following the December 1995 negotiations with DowElanco. The following underlying assumptions differ from the October 1995 HED risk assessment: 20 year career span for custom operators, 30 year career span for private growers, use of monitoring data from the Ainger, NC "traveller" study to replace the Arizona drum data, use of respirators during both loading and application tasks, restriction of Telone application to a distance 300 meters from an occupied structure. BEAD has provided new information on length of career (Zavolta and Michell 1996). Data from the Ainger, NC "traveller" study were submitted by DowElanco during the December 1995 negotiations. (The "traveller is a 1000-gal minibulk loading system that will replace drums in some parts of the country.) The respirator and buffer zone requirements are additional mitigation measures required on the Telone label as an outcome of the December 1995 negotiations.

The excess individual lifetime cancer risk estimates for occupational exposure range from 4.5×10^{-5} to 1.1×10^{-6} for custom operators[7] and from 3.6×10^{-5} to 3.1×10^{-6} for growers using typical mitigation measures. Cancer risk estimates for residents/bystanders range from 9.7×10^{-6} to 1.0×10^{-6} for stationary individuals at a fixed distance 125 meters (~300 feet) from a treated field (at the edge of the buffer zone). The resident/bystander

[7] custom loaders and applicators

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risks may be overestimates because individuals are unlikely to spend 16 hours/day at a fixed distance for 30 years. Also, the population of area residents living at the edge of the buffer zone is expected to be small, according to limited 1992 population survey data from DowElanco (Mehta 1994c). The population survey of states comprising 95% of Telone usage showed that 3,345 people (1088 residences) lived within 1 mile of Telone treated fields (Mehta 1994c). There are no data on the number of people residing within 300 feet of treated fields.

The following mitigation measures are likely to further reduce exposure to Telone and associated cancer risk: reduced maximum application rates, increased soil injection depth, soil sealing, and shank placement. These mitigation measures are likely to further reduce risks to private growers, custom operators, and area residents/bystanders. However, the actual impact of these measures on reducing risk cannot be quantified.

B. Strengths, Weaknesses, and Uncertainties of the Risk Assessment

The occupational and residential risk assessment for Telone contains strengths and uncertainties based on the existing toxicological and exposure data, data gaps, and gaps in scientific knowledge. This assessment uses standard assumptions regarding human body weight, worklife, time of residence, and other exposure parameters; interspecies extrapolation; and exposure prorated over a lifetime to estimate cancer risks. Strengths and uncertainties of the assessment are described below.

The existing evidence for the inhalation carcinogenicity endpoint is strong. Telone was carcinogenic in laboratory animals by both the inhalation and oral routes of exposure. Carcinogenicity was confirmed by mouse and rat oral carcinogenicity studies; multiple tumor types were seen. Further, bronchioalveolar adenoma, the tumor chosen for quantitative risk assessment, was noted in both the inhalation and oral studies in the mouse. The positive results in bacterial, Drosophila, and mammalian cell mutagenicity studies also contribute to the weight of evidence for carcinogenicity. Telone is structurally similar to vinyl chloride and epichlorohydrin, two other short chain chlorinated hydrocarbons which are known carcinogens (Dearfield 1989). Telone is therefore classified as a Group B2, probable human carcinogen.

There is limited evidence for the heritable mutation endpoint. The positive results in the Drosophila sex-linked recessive lethal assay indicate that Telone may produce heritable mutations. The germ cell effects must be confirmed by additional testing in a mammalian species in vivo, namely by an alkaline elution assay in testicular cells. HED has already requested these data and a DCI will soon be issued for these test data. Positive results in the alkaline elution assay might indicate the need for additional testing (e.g., heritable translocation or mouse specific locus assay) and risk assessment for this endpoint.

The existing exposure monitoring data indicate the magnitude of potential exposure to growers, custom operators, and residents/bystanders near Telone-treated fields. There are

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many uncertainties inherent in exposure monitoring for this or any fumigant. Soil conditions (moisture, organic content, temperature), soil sealing method, injection depth, and meteorological conditions all impact Telone air concentrations to various degrees.

The exposure monitoring data suggest uncertainties regarding the efficacy of certain mitigation measures, including use of enclosed cabs and dry disconnects. The monitoring data did not show enclosed cabs to provide any reduction in exposure, possibly because applicators frequently left the enclosed cab to perform various tasks during Telone application. Dry disconnects appear to offer some exposure mitigation. Exposure reduction with dry disconnects could be quantified with the short-term sampling data but not with the 4-hour sampling data. The 4-hour sampling data suggest an increase in exposure with the use of dry disconnects, which is counter-intuitive. This may be due to a low number of sampling replicates and inherent variability in the data. There are no data to demonstrate the efficacy of other mitigation measures, including different injection depths, different soil sealing methods, minimum soil moisture and temperature requirements, and bulk or minibulk loading systems, although all of these measures are expected to decrease exposure.

The exposure estimates provided in this assessment are derived by extrapolating from the existing exposure monitoring studies (on a limited number of crops) to many crops. HED determined that this extrapolation was appropriate because crop specific parameters, such as foliage type, do not impact Telone volatilization. However, this extrapolation is an over simplification which does not account for local environmental conditions, such as differences in soil temperature, soil type, soil moisture, or meteorological conditions. This extrapolation does not account for differences in application rate, application method, injection depth, or soil sealing measures. Telone is a preplanting fumigant, and annual land use, and risk associated with particular crops, may vary. Actual land use may be driven by weather conditions, pests, and market pressures.

The greatest uncertainty in Telone exposure is the relative importance of various crop and site specific parameters listed above and their relationship to one another.

There are also uncertainties regarding practices of commercial operators. Exposure and risk estimates provided assume that commercial operators treat only one crop. Risk may be underestimated for commercial operators treating specialty crops in the Pacific Northwest.

Given the uncertainties described above, HED has medium confidence in the exposure estimates derived from the air monitoring data. Likewise, HED has medium confidence in the risk estimates provided herein.

C. Summary/Conclusions

HED has provided an assessment of occupational and residential/bystander risks associated with the major uses of Telone. This risk assessment provides cancer risk estimates for agricultural uses of Telone. Cancer risks were estimated using a linear low-

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dose extrapolation model (Q_1^*). The excess individual lifetime cancer risk estimates for Telone range from 4.5 X 10^{-5} to 1.1 X 10^{-6} for custom operators[8] and from 3.6 X 10^{-5} to 3.3 X 10^{-6} for private growers. Cancer risk estimates for residents/bystanders range from 9.7 X 10^{-6} to 1.0 X 10^{-6} for individuals living or working at a fixed distance 125 meters from a treated field, at the edge of the buffer zone. The resident/bystander risks are conservative estimates which assume exposed individuals spend 16 hours/day at the edge of the buffer zone around treated fields for 30 years. HED believes it is unlikely that individuals will actually spend 16 hours/day at a fixed distance for 30 years.

Many of HED's concerns for cancer risk to growers, custom loaders, and applicators, and area residents exposed to Telone from agricultural use have been addressed with the new mitigation measures. HED believes that the proposed exposure mitigation measures may reduce exposure and risk. HED has been able to quantify exposure and risk reduction from implementation of buffer zones, and from use of respirators, bulk or minibulk loading, and an increased reentry interval. Other mitigation measures are expected to provide additional reductions in exposure and risk that can not be quantified. Reduced maximum application rates, increased injection depth, soil sealing, and soil moisture and temperature requirements are all expected to reduce Telone exposures; however, exposure reduction from these specific measures can not be quantified with the available data.

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[8] custom loaders and applicators

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Table 1. Exposure and Cancer Risk Estimates for Custom Loaders and Applicators.

Crop/Scenario	Telone Air Concentration		Exposure Duration			LADE[c], mg/kg/day with mitigation	Excess Individual Cancer Risk Estimate	Comments
	$\mu g/m^3$	data source[a]	hours/ day	days/ year	data source[b]			
Sugar Beets	Major Use States: WY, NE, ID, CO							
loader	1198	AZ bulk	6	9	WY usage	1.3 E-4	6.7 E-6	AZ drum data used previously for loaders
applicator[d]	5650	AZ bulk	6	9	WY usage	1.1 E-4	6.0 E-6	AZ drum data used previously for applicators
Cotton	Major Use States: AZ, GA, AL, SC							
loader	1198	AZ bulk	10	36	AZ usage	8.4 E-4	4.5 E-5	AZ drum data used previously
applicator	5650	AZ bulk	10	20	AZ usage	4.2 E-4	2.2 E-5	
Tobacco	Major Use States: NC, GA, SC							
loader	359	NC traveler	5	10	NC usage	3.5 E-5	1.9 E-6	NC drum data used previously
applicator	1287	NC traveler	5	10	NC usage	1.3 E-4	6.7 E-6	AZ bulk data used previously
Potatoes	Major Use States: WA, ID, OR, FL, NV							
loader	1198	AZ bulk	8	24	WA usage	4.5 E-4	2.4 E-5	WA bulk data used previously
applicator	1742	WA bulk	8	24	WA usage	1.2 E-4	6.6 E-6	

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Crop/Scenario	Telone Air Concentration		Exposure Duration			LADE[c], mg/kg/day with mitigation	Excess Individual Cancer Risk Estimate	Comments
	μg/m³	data source[a]	hours/ day	days/ year	data source[b]			
Onions	Major Use States: WA, OR, ID, NV							
loader	1198	AZ bulk	8	4	WA usage	7.5 E-5	4.0 E-6	NC drum data used previously
applicator	1742	WA bulk	8	4	WA usage	2.1 E-5	1.1 E-6	AZ drum data used previously
Carrots	Major Use States: WA, TX							
loader	1198	AZ bulk	8	7	WA usage	1.3 E-4	7.0 E-6	AZ drum data used previously
applicator	1742	WA bulk	8	7	WA usage	3.6 E-5	1.9 E-6	AZ drum data used previously

[a] Air concentrations are from one of 3 worker monitoring studies (Harquahala Valley, AZ; Ainger, NC; or Moses Lake, WA) using a minibulk or bulk loading and row or broadcast application; monitored air concentrations are presented as geometric mean to give the best estimate of central tendency.

[b] Exposure duration is based on usage data from the DowElanco DCI from the state using the most Telone (PV) for a particular crop.

[c] Reflects respirator requirement all activities from proposed Telone label, and a 90% exposure reduction (protection factor of 0.10).

[d] Applicator LADE was adjusted with a protection factor of 0.19 for end row spillage control to reflect engineering control requirements from existing Telone labels; loader LADE was not adjusted for dry disconnects because this was not supported by the 4-h monitoring data.

[e] Applicator LADE not adjusted for spill control because LADE estimate based on Ainger, NC traveler data, which used spill control.

[f] Assumes annual treatment, which may overestimate exposure.

Extra cancer risk = Q_1^* X LADE, where $Q_1^* = 5.3 \times 10^{-2}$ (mg/kg/day)$^{-1}$ and

$$\text{LADE (mg/kg/day)} = \frac{(\text{air concentration, } \mu g/m^3)(1 mg/1000\ \mu g)(\text{ventilation rate, } m^3/hr)(hr/day)(days/yr)(1\ yr/365\ days)(yrs\ exposed/70\ yrs)}{70\ kg\ body\ wt}$$

Assumptions: ventilation rate = 1.74 m³/h, worklife = 20 yrs, average lifetime = 70 yrs, body wt = 70 kg. Equivalent daily exposure duration assumed for custom loaders and applicators.

Table 2. Exposure and Cancer Risk Estimates for Private Growers Using Telone

Crop/Scenario	Telone Air Concentration		Exposure Duration			LADE[c,d], mg/kg/day with mitigation	Excess Individual Cancer Risk Estimate	Comments
	μg/m³	data source[a]	hours/ day	days/ year	data source[b]			
Crucifers	Major Use State: AZ							
loading	18371	AZ bulk	1.25	4	AZ usage	1.7 E-4	--	AZ drum data previously used
application	5650	AZ bulk	8	4	AZ usage	1.0E-4	--	
grower[d] total	--	--	9.25	4	AZ usage	2.7 E-4	1.4 E-5	
Peppers	Major Use State: NM							
loading	359	NC traveler	0.5	3	NM usage	1.6 E-6	--	AZ drum data previously used no PF for dry disconnects
application	1287	NC traveler	5	3	NM usage	5.6 E-5	--	AZ bulk data previously used no PF for spill control
grower total	--	--	5.5	3	NM usage	5.8 E-5	3.1 E-6	
Cucurbits	Major Use States: TX, NC, SC, CA							
loading	18371	AZ bulk	0.25	15	TX usage	1.3 E-4		AZ drum data previously used
application	5650	AZ bulk	6	15	TX usage	2.8 E-4		
grower	--	--	6.25	15	TX usage	4.10 E-4	2.2 E-5	

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Crop/Scenario	Telone Air Concentration		Exposure Duration			LADE[c,d], mg/kg/day with mitigation	Excess Individual Cancer Risk Estimate	Comments
	$\mu g/m^3$	data source[a]	hours/ day	days/ year	data source[b]			
Sugar Beets	Major Use States: WY, NE, ID, CO							
loading	18371	AZ bulk	0.5	1.5	WY usage	2.5 E-5	--	AZ drum data previously used
application	5650	AZ bulk	8	1.5	WY usage	3.8 E-5	--	AZ drum data previously used
grower	--	--	8.5	1.5	WY usage	6.3 E-5	3.4 E-6	
Cotton	Major Use States: AZ, GA, AL, SC							
loading	18371	AZ bulk	1.25	7	AZ usage	3.0 E-4	--	AZ drum data previously used
application	5650	AZ bulk	8	7	AZ usage	1.8 E-4	--	
grower	--	--	9.25	7	AZ usage	4.8 E-4	2.5 E-5	
Tobacco	Major Use States: NC, GA, SC							
loading	359	NC traveler	0.5	3.5	NC usage	1.8 E-6		NC drum data previously used no PF for dry disconnects
application (row)	1287	NC traveler	5	3.5	NC usage	6.6 E-5	--	AZ bulk data previously used no PF for spill control
grower	--	--	5.5	3.5	NC usage	6.8 E-5	3.6 E-6	

Crop/Scenario	Telone Air Concentration		Exposure Duration			LADE[c,d], mg/kg/day with mitigation	Excess Individual Cancer Risk Estimate	Comments
	$\mu g/m^3$	data source[a]	hours/ day	days/ year	data source[b]			
Potatoes	Major Use States: WA, ID, OR, FL, NV							
loading	18371	AZ bulk	0.5	4	WA usage	6.8 E-5	--	WA bulk data previously used
application	1742	WA bulk	10	4	WA usage	3.9 E-5	--	
grower	--	--	10.5	4	WA usage	1.1 E-4	5.7 E-6	
Sweet Potatoes	Major Use States: NC, TX, SC							
loading	18371	AZ bulk	0.5	2	NC usage	3.4 E-5	--	AZ drum data previously used
application	5650	AZ bulk	5.5	2	NC usage	3.5 E-5	--	
grower	--	--	6.0	2	NC usage	6.9 E-5	3.7 E-6	
Peanuts	Major Use States: GA, AL, TX							
loading	359	NC traveler	1	5	GA usage	5.2 E-6	--	AZ bulk data previously used no PF for dry disconnects
application	1287	NC traveler	3	5	GA usage	5.6 E-5	--	AZ drum data previously used no PF for spill control

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Crop/Scenario	Telone Air Concentration		Exposure Duration			LADE[c,d], mg/kg/day with mitigation	Excess Individual Cancer Risk Estimate	Comments
	μg/m³	data source[a]	hours/ day	days/ year	data source[b]			
grower	--	--	4	5	GA usage	6.2 E-5	3.3 E-6	
Fruit/Nut Trees and Grapevines[e]		Major Use State: SC						
loading	359	NC traveler	1.5	4	SC usage	6.3 E-6	--	NC drum data previously used no PF for dry disconnects
application	1287	NC traveler	5	4	SC usage	7.5 E-5	--	AZ drum data previously used no PF for spill control
grower	--	--	6.5	4	SC usage	8.1 E-5	4.3 E-6	
Onions	Major Use States: WA, OR, ID, NV							
loading	18371	AZ bulk	0.5	5	WA usage	8.6 E-5	--	NC drum data previously used
application	1742	WA bulk	10	5	WA usage	4.8 E-5	--	AZ drum data previously used
grower	--	--	10.5	5	WA usage	1.3 E-4	6.9 E-6	
Tomatoes	Major Use States: TX, HI, FL, AL							
loading	18371	AZ bulk	1	3	AL usage	1.0 E-4	--	AZ drum data previously used

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Crop/Scenario	Telone Air Concentration		Exposure Duration			LADE[c,d], mg/kg/day with mitigation	Excess Individual Cancer Risk Estimate	Comments
	μg/m³	data source[a]	hours/ day	days/ year	data source[b]			
application	5650	AZ bulk	8	3	AL usage	7.5 E-5	--	
grower	--	--	9	3	AL usage	1.8 E-4	9.5 E-6	
Carrots	Major Use States: WA, TX							
loading	18371	AZ bulk	0.5	3	WA usage	5.1 E-5		AZ drum data previously used
application	5650	AZ bulk	10	3	WA usage	9.4 E-5		AZ drum data previously used
grower	--	--	10.5	3	WA usage	1.5 E-4	7.8 E-6	
Pineapple[e]	Major Use State: HI							
loading	18371	AZ bulk	1.25	11	HI usage	4.7 E-4	--	NC drum data previously used
application	5650	AZ bulk	6	11	HI usage	2.1 E-4	--	
grower	--	--	7.25	11	HI usage	6.8 E-4	3.6 E-5	

[a] Air concentrations are from one of 3 worker monitoring studies (Harquahala Valley, AZ; Ainger, NC; or Moses Lake, WA) using minibulk or bulk loading and row or broadcast application; monitored air concentrations are presented as geometric mean to give the best estimate of central tendency.
[b] Exposure duration is based on usage data from state using the most Telone (PV) for a particular crop.
[c] Reflects respirator requirement for loading and other direct contact activities from Telone label.
[d] Grower LADE and risk estimates are based on the sum of LADE estimates for the loading and applying Telone. Total LADE was adjusted with a protection factor of 0.10 for respirators. LADE for loaders was adjusted for a protection factor of 0.64 for dry disconnects; LADE for applicators was adjusted with a protection factor of 0.19 for end-row spillage control. Data from NC traveller study were not adjusted for dry disconnects or spill

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control because these mitigation measures were included in the study.

LADE (mg/kg/day) = (air concentration, $\mu g/m^3$)(1mg/1000 μg)(ventilation rate, 1.74 m^3/hr)(hr/day)

$$\frac{\text{(days/yr)(1 yr/365 days)(30 yrs exposed/70 yrs)}}{\text{70 kg body wt}}$$

[a] Assumes annual treatment, which may overestimate exposure.

Extra cancer risk = Q_1^* X LADE, where Q_1^* = 5.3 X 10^{-2} $(mg/kg/day)^{-1}$ and LADE is calculated by the formula given above.

Table 3. Cancer Risk Estimates for Residents/Bystanders near Telone Treated Fields[a]

Distance from Field (meters)	Mean Air Concentration[a] Using Pooled Data, μg/m³	Lifetime Average Daily Exposure (mg/kg/day)	Cancer Risk Estimates	
			1 application/year	2 applications/year
Moses Lake, Washington Study (Telone II, 25 gal/acre, broadcast, loamy sand)				
5	73.6	2.4 E-4	1.3 E-5	2.6 E-5
25	62.1	2.0 E-4	1.1 E-5	2.2 E-5
125	40.2	1.3 E-4	7.0 E-6	1.4 E-5
BUFFER ZONE				
500	17.2	5.6 E-5	3.0 E-6	6.0 E-6
800	14.6	4.8 E-5	2.5 E-6	5.1 E-6
Harquahala Valley, AZ Study[b] (Telone II, 12 gal/acre, row, sandy loam)				
5	104.7	3.4 E-4	1.8 E-5	3.6 E-5
25	112.4	3.7 E-4	2.0 E-5	3.9 E-5
125	55.6	1.8 E-4	9.7 E-6	1.9 E-5
BUFFER ZONE				
500	11.8	3.9 E-5	2.1 E-6	4.1 E-6
800	6.5	2.1 E-5	1.1 E-6	2.3 E-6
1200	3.8	1.3 E-5	6.7 E-7	1.3 E-6
1600	2.4	7.8 E-6	4.2 E-7	8.3 E-7
Hookerton, NC Study (Telone C-17, 20 gal/acre, broadcast, sandy loam)				
5	21.7	7.1 E-5	3.8 E-6	7.5 E-6
25	15.1	4.9 E-5	2.6 E-6	5.2 E-6
125	6.0	2.0 E-5	1.0 E-6	2.1 E-6
BUFFER ZONE				
500	1.5	5.0 E-6	2.6 E-7	5.3 E-7
800	1.3	4.1 E-6	2.2 E-7	4.4 E-7

[a] Values are arithmetic means. [b] Exposure monitoring in the Arizona study was performed at two additional points, 1200 and 1600 meters from treated field.

Extra cancer risk = Q_1^* X LADE, where $Q_1^* = 5.3 \times 10^{-2}$ (mg/kg/day)$^{-1}$ and

LADE (mg/kg/day) = (air concentration, μg/m³)(1mg/1000 μg)(ventilation rate, 0.81 m³/hr)(16 hr/day)(15 days/yr)(1 yr/365 days)(30 yrs/70 yrs) / 70 kg body wt

Assume Telone applied 15 days/application event for all crops, with 1 or 2 events/year. Indoor and outdoor air concentrations of Telone are equivalent.

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