Department of Pesticide Regulation

Paul Helliker
Director

Arnold Schwarzenegger
Governor

M E M O R A N D U M

TO: Andrew Yokoyama, Pesticide Use Specialist

HSM-04015
This number was assigned after distribution

FROM: Worker Health and Safety Branch

DATE: May 5, 2004

SUBJECT: PESTICIDE PRODUCT LABEL EVALUATION

PRODUCT NAME	:	Telone C-17 CA
ACTIVE INGREDIENT(S)	:	(81.2%) 1,3-DICHLOROPROPENE (telone) (16.5%) CHLOROPICRIN
I.D. NUMBER	:	204019
DOCUMENT NUMBER	:	50046-0183 (also attached with ID No. 204020)
EPA REGISTRATION NO.	:	62719-12
COMPANY NAME	:	Dow AgroSciences LLC

REGISTRATION TYPE: Section 3

LABEL AMENDMENT: Yes ☒ No ☐

JUSTIFICATION/ADDITIONAL DATA REQUIRED: Yes ☐ No ☒

PROPOSED REGISTRATION ACTION: Do Not Recommend Registration

U.S. EPA RED ISSUED FOR THIS A.I.: Yes ☒ No ☐

SUMMARY OF REGISTRATION REQUEST:
Dow AgroSciences LLC is requesting label amendments for the current registered Section 3 product, Telone C-17 CA, EPA Reg No. 62719-12. These label amendments are: 1) revised First Aid statements; 2) reduced the "buffer zone" from 300 feet to 100 feet; 3) amended the personal protective equipment (PPE) section to reflect handlers' potential exposure during certain tasks that may involve direct liquid contact (e.g., fumigant transfer, equipment calibration) or indirect liquid contact (e.g., soil sealing, broadcasting, row product application); 4) added the statement "Telone C-17 CA shall not be applied to soils more frequently than once each year;" 5) added the handlers' respirator PPE requirement when the air concentration of chloropicrin is ≥ 0.1 ppm; 6) removed the word POISON and the skull and crossbones symbol from the labeling and changed the precautionary statements for acute inhalation from Toxicity Category I to II; and 7) added the statement "….in cropland in California." The Worker Health and Safety (WHS) Branch has interpreted the 7th amendment to mean "for California use only." This product is a pre-plant liquid fumigant for agriculture uses (row, field, fruit, nut, and nursery crops). It is applied via shank injection using ground equipment. When injected, a minimum of

12 inches depth is required, including the nearest soil/air interface. Chemigation is not permitted, and it cannot be applied in greenhouses or other enclosed areas.

The U.S. Environmental Protection Agency (U.S. EPA) has completed a Reregistration Eligibility Decision (RED) for 1,3-dichloropropene (U.S. EPA, 1998b). The U.S. EPA has not published a chloropicrin RED.

The reported acute toxicity data were determined by the Medical Toxicology Branch (MT) to be Toxicity Category I for primary dermal irritation and Toxicity Category II for acute oral (Moore, 1999). MT determined that the reported acute dermal toxicity data were unacceptable and not required because of the primary dermal irritation hazard (Moore, 1999). Also, MT indicated the eye irritation acute toxicity data were not required because the labeling indicated a Toxicity Category I (Moore, 1999), and the reported acute inhalation toxicity data were unacceptable and not required because the labeling indicated a Toxicity Category I (Moore, 2000). It was a dermal sensitizer in the animal model tested (Johnson, 1998).

BASIS FOR PROPOSED ACTION:
The label required respiratory PPE and the closed cab criteria are consistent with Title 29, Code of Federal Regulations, Part 1900, Section 134 (19 CFR 1910.134), the American Society of Agricultural Engineers (1998), the National Institute for Occupational Safety and Health Pocket Guide to Chemicals (NIOSH, 2003), the U.S. EPA's RED for 1,3-dichloropropene (U.S. EPA, 1998b), 40 CFR 170.240(d)(5)[closed cabs], and Pesticide Registration (PR) Notice 98-9 (U.S. EPA, 1998a). The First Aid statements and the 'Note to Physician' are consistent with PR Notice 2001-1 (U.S. EPA, 2001).

However, WHS is not recommending registration at this time for the following reasons:

1. A WHS review of the registrant's air-monitoring data indicates the potential for both acute (non-cancer) and chronic (cancer) adverse health effects associated with the use of a 100-foot buffer zone (see attached review of data by Powell, 2004). As indicated in the Powell (2000 and 2004) memos, potential adverse health effects associated with the use of a 300-foot buffer zone are marginal at best. With smaller buffer zones, and unlimited acreages, the potential for adverse health effects become more pronounced. Therefore, WHS feels that the registrant's request to reduce the buffer zone from 300 to 100 feet on the proposed amended label does not adequately minimize the potential adverse health effects to bystanders; thus registration of the proposed label is not recommended.

2. The acute inhalation precautionary statements do not adequately mitigate any inadvertent inhalation exposure during use (see Additional Comments).

ADDITIONAL COMMENTS:
As noted by Powell (2004), the 300-foot buffer zone may not be adequately protective and should be addressed in the finalized risk characterization. On an interim basis, WHS

recommends that the current buffer zone of 300 feet be maintained until DPR finalizes the risk characterization of 1,3-dichloropropene. Due to the adverse health concerns based on both acute and chronic exposure, any buffer zone exemptions based on frequency of application would not be appropriate. Based on the above-mentioned reviews, the exposure concerns may be minimized when treated acreages are limited. We recommend, therefore, that buffer zone reductions below 300 feet should only be permitted under the following circumstances:

1. A minimum of a 100-foot buffer zone may be adequate if the maximum treatment area is limited to 20 acres, and;
2. A minimum of a 200-foot buffer zone may be adequate if the maximum treatment area is limited to 40 acres.

The following should be brought to the attention of MT. The proposed amended labeling does not show the word POISON and the skull and crossbones symbol. The acute inhalation precautionary narration is for Toxicity Category II. MT determined that the subject product was a Toxicity Category I for acute inhalation (Moore, 2000). WHS recommends that MT re-evaluate the acute inhalation precautionary narration.

The following should be called to the attention of the registrant:

1. The 'if inhaled' First Aid antidote recommends mouth-to-mouth resuscitation. However, the current medical advice suggests that chest compression alone may be just as effective (Ewy, 2000; Hallstrom et al., 2000). According to Dr. Michael O'Malley (WHS Medical Consultant, personal communication on April 23, 2004), the Note to Physician is adequate as are the dermal, eye, and ingestion First Aid statements. However, it may not be medically advisable for the subject product's inhalation First Aid statements to recommend mouth-to-mouth resuscitation because of the likelihood of an inhalation adverse health effect to the person performing the artificial respiration. Ewy (2000) and Hallstrom et al. (2000) suggest chest compression alone may be just as effective as chest compression plus rescue breathing (i.e., mouth-to-mouth resuscitation).

The WHS Senior Industrial Hygienist concurs with the above evaluation of label respiratory PPE (personal communication with Harvard Fong on April 28, 2004).

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Powell, S. 2004. Review of data to support request to decrease buffer zone for 1,3-dichloropropene to 100 feet (tracking id # 204019, # 204020 and # 205697). Memo to Joseph Frank, Senior Toxicologist, Worker Health and Safety Branch, dated April 22, 2004. Sacramento, CA: Worker Health and Safety Branch, Department of Pesticide Regulation, California Environmental Protection Agency.

U.S. EPA. 1998a. Pesticide Registration Notice 98-9 (PR Notice 98-9), Modification of respirator statements for pesticide product labels, dated October 1998. Washington, D.C.: Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency.

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Label evaluation by: [original signed by J. Johnson]
Joshua L. Johnson
(Associate Environmental Research Scientist

Memo reviewed by: [original signed by J. Frank for D. DiPaolo]
Donna DiPaolo, Ph.D.
(Associate Toxicologist)

Department of Pesticide Regulation

Paul Helliker
Director

Arnold Schwarzenegger
Governor

TO: Joseph Frank, Senior Toxicologist
Worker Health and Safety Branch

FROM: Sally Powell, Senior Environmental Research Scientist *[original signed by S. Powell]*
Worker Health and Safety Branch
916-445-4248

DATE: April 22, 2004

SUBJECT: REVIEW OF DATA TO SUPPORT REQUEST TO DECREASE BUFFER ZONE FOR 1,3-DICHLOROPROPENE TO 100 FEET (REGISTRATION TRACKING ID #204019, #204020 AND #205697)

I was asked to evaluate whether the U.S. Environmental Protection Agency (U.S. EPA) report (Weiss, 2002) submitted by Dow AgroSciences (Dow) supports Dow's request to reduce the buffer zone from 300 to 100 feet for three 1,3-dichloropropene (1,3-D) products.

Requested change

Prior to May 2003, labels for 1,3-D products applied by soil injection required 300-ft buffer zones (zones around treated fields, inside which all structures must remain unoccupied until 7 days after an application). The labels allowed a field that would not be treated with 1,3-D again for at least 3 calendar years to be treated with *no* buffer zone. However, California permit conditions (DPR, 2002) require a 100-ft buffer zone for those fields that would otherwise be exempted by the labels from any buffer zone.

Dow requested label changes to reduce buffer zones from 300 to 100 feet for 3 of its 1,3-D products. The once-in-3-years exemption would still apply. U.S. EPA approved that element of the label change (letter from Mary Waller, Registration Division, U.S. EPA, to Bruce Houtman, Dow AgroSciences, stamped April 21, 2003; included with the DPR data package), which was implemented on the May 29, 2003 labels.

Dow has submitted the same proposed label changes to DPR in this data package. The three products at issue, Telone II, Telone C-17, and Telone C-35, account for about 95 percent of the 1,3-D applied in California, according to Chemical Data Management Systems (CDMS) data for 2001.

Data in support of the requested change

Submitted with the Dow request is a U.S. EPA review memo (Weiss, 2002) addressing the potential risks to bystanders of reducing 1,3-D buffer zones from 300 to 100 feet. I had previously reviewed the Weiss memo (Powell, 2002). Weiss reviewed and reanalyzed data from 14 registrant studies that monitored off-site air concentrations during and after 1,3-D applications.

Lifetime cancer risk

Weiss estimated lifetime cancer risk separately for each monitored application, using the highest average air concentration over the monitoring period (range from 7-15 days) in any one direction from the field. He assumed that a person was exposed to that concentration for 2 hrs/day, 7-15 days/yr, for 30 years of a 70-yr lifetime, and used the same UCL potency used by the Department of Pesticide Regulation (DPR) (0.055 per mg $kg^{-1}d^{-1}$) in its risk characterization for 1,3-D (DPR, 1997). Excluding drip applications and three others at rates under 57 lbs/ac (only 4 percent of California applications are made at such low rates), lifetime cancer risks calculated by Weiss ranged from $1.9x10^{-6}$ to 3.8×10^{-5} at 100 feet (5 monitored applications). At 200 feet (1 application), lifetime risk was $4.5x10^{-6}$. At 300 feet (1 application), lifetime risk was $3.9x10^{-5}$. At 400 feet (3 applications), lifetime risk ranged from $1.8x10^{-6}$ to 1.9×10^{-5}.

While DPR uses a more refined method for estimating long-term exposures to 1,3-D, I concluded that Weiss' method was more likely to underestimate than overestimate the cancer risk, and concluded the data supported his conclusion that even the existing 300-ft buffer zone could result in cancer risks greater than $1x10^{-6}$ to residents of homes near treated fields.

Short-term risk

Weiss estimated short-term (noncancer) risk using the highest 7-day average concentration in any one direction from each treated field. He calculated MOEs for each monitored application for two application rates (the actual study rate and the maximum label rate for food crops) and two exposure durations (2 hrs/day and 16 hrs/day, for 7 days). It was not clear to me whether these MOE would be for children or adults. WHS would estimate exposure resulting from a single application using the maximum application rate. For residential exposures of only 7 days duration, WHS would probably use the 16-hr/day exposure scenario. Eight applications reviewed by Weiss had concentrations measured at 100 feet from the field. Their MOEs at maximum application rate and 16 hrs/day exposure ranged from 43 to 360; another application that monitored at 200 feet had an margins of exposures (MOE) of 450.

These MOE were based on a No Observed Adverse Effect Level (NOAEL) of 20 ppm, while DPR has a subchronic No Observed Effect Level (NOEL) of 10 ppm. However, other differences in the calculation of MOEs make it hard to compare ours to theirs.

Acute risk

Weiss also concluded there was no evidence of acute risk with the 100-ft buffer. The MOE was 630 for the maximum measured 4-hr concentration at any application. This was based on an acute endpoint of 454 ppm. Again, I could not determine whether this MOE was for children or adults. DPR does not have a 4-hr endpoint for 1,3-D.

Acute Reference Concentration (RfC)

DPR's 24-hour reference concentration (RfC) for 1,3-D is 200 μg m^{-3}, based on children's average breathing rate of 0.46 m^3 kg^{-1} d^{-1} (Reed, 2001). If the proposed default breathing rate for children of 0.59 m^3 kg^{-1} d^{-1} is used, the RfC is 156 μg m^{-3} (Andrews and Patterson, 2000).

Off-site air monitoring data

I examined the data from several of the studies that Weiss reviewed. These studies included data on six applications of Telone II. I determined the highest measured 24-hr concentration in any direction from each monitored application (Table 1) for comparison with the acute RfC. This differs from the way off-site monitoring data is sometimes summarized by the registrant, which is by averaging the concentrations found in all directions from a field (e.g., Petty, 2001). WHS assumes that a child could live in a residence close to and in the downwind direction from a treated field, and could spend 24 consecutive-hours at the residence, or that it should be safe for a child to do so. (We do not distinguish between indoor and outdoor concentrations, noting that under some conditions, indoor concentrations can be as high as outdoor.)

Whether or not end-row spillage controls were used in these studies is important because it could substantially affect the off-site concentrations, but I could not determine whether they were used. They were probably *not* used in the Houtman or Petty studies, because these applications were made before spill controls were required by the Telone II label. They probably *were* used in the Rotondaro study, which was conducted in October-November 2000, after the spill-control requirement was added to the product label in October 1998.

In Houtman (1992), 24-hr concentrations above the RfC of 200 μg m^{-3} were measured at 82 and 410 feet from the field following one application. The two applications reported by Rotondaro (2001) had high concentrations (636 and 187 μg m^{-3}) at 100+ feet; no other distances were monitored. Note that even the lower of the two is above 156 μg m^{-3}, the RfC for children based on the proposed default breathing rate (Andrews and Patterson, 2000).

Concentrations were much lower at the three applications reported by Petty (2001), even at 100 feet from the fields. Treated acreage and application rates were lower in the Petty applications than in the other studies. They were also lower than the typical application in California, where the mean size of a 1,3-D soil-injection application in 2001 was 23 acres and the mean application rate was 200 lbs/ac (according to CDMS data). The last column of Table 1 gives the maximum measured concentration adjusted proportionally to the maximum permitted application rate for Telone II (332 lbs/ac). The validity of this adjustment is suspect, but lacking actual data at the maximum rate, WHS generally makes the adjustment. When adjusted for the maximum application rate, one of the three applications in Petty also exceeds 156 μg m^{-3}.

Previous assessment of acute risk from reduced buffer zone using modeling results

In 2000, Dow provided DPR with modeling results of 1,3-D concentrations resulting from tree and vine applications (Cryer and van Wesenbeeck, 2000). Trees and vines are typically treated at higher rates (often at the maximum) than other crops, but any given field is treated less frequently because the crop is permanent. In order to examine the acute risk from these high-rate applications, DPR requested a subset of near-field receptor results from the overall modeling output (Johnson, 2000). From the data produced by modeling 20 years of daily air concentrations, Cryer and van Wesenbeeck (undated) extracted all air concentrations for the 24-hour periods beginning 2 and 3 days following applications, for the receptors located 100 to 1000 feet (in 100-ft increments) from treated fields. Using these data, I calculated the 95th percentile air concentration for each distance and field size (Powell, 2000). I then calculated 24-hr absorbed dose (mg kg^{-1} d^{-1}) for each distance and field size, using the same breathing rates assumed in the DPR risk characterization, 0.46 and 0.23 m^3 kg^{-1} d^{-1}, for children and adults respectively. Using my estimates, Reed (2000) calculated the MOE corresponding to the absorbed dose at each distance and field size, for both children and adults. She then presented the buffer zone width needed to achieve a child MOE of 100 for each field size represented in the modeling by Cryer and van Wesenbeeck. For a treated field of 11.3 acres, a buffer zone of between 100 and 200 feet was needed. For the largest field modeled, 74.4 acres, a buffer zone of between 400 and 500 feet was needed. It was subsequently recommended to the director that permit conditions for Telone applications to permanent crops require buffer zones of 100 feet up to 20 acres, 200 feet for 40 acres, and that these applications be limited to a maximum of 40 acres (Gosselin, 2001). This recommendation was not implemented.

Conclusion

The data reviewed by Weiss (2002) indicate that, with a 100-ft buffer zone, unacceptable lifetime (cancer), short-term (7-day) and acute (24-hr) exposures would all be possible. In fact, these data indicate that the existing 300-ft buffer zone may not be sufficient to protect against cancer or acute risks.

Modeling results previously analyzed by DPR staff (Powell, 2000; Reed, 2000) also indicated that in order to have MOEs $\geq$ 100 for children's 24-hr exposure, buffer zones greater than 100 ft were needed for all but the smallest treated fields; 200-ft buffers were needed for 28-ac applications, and buffers of 400-ft were needed for 58-ac applications.

Recommendations

- The buffer zone should not be reduced to 100 ft before a full risk characterization is done.
- Until the full risk characterization is done, DPR should consider revising the permit conditions to make the buffer zone 300 feet for all applications, including applications to fields treated no more than once in 3 years.

- When the full risk characterization is done, the adequacy of the 300-ft buffer zone to protect against lifetime, seasonal and acute risks should be reexamined carefully.

Table 1. Maximum 24-hr air concentration in any direction from fields treated with 1,3-dichloropropene (Telone II).

Source	Application				Highest 24-hr air concentration		
	Location and year	Method	Acres treated	Rate (lbs ai/ac)	Distance from field (ft)	Measured ($\mu g\ m^{-3}$)	Adjusted [a] ($\mu g\ m^{-3}$)
Houtman (1992)	WA 1992	Broadcast, untarped, 16-18" deep	20	246	82 410	203 245	274 331
Rotondaro (2001)	FL 2000	Bedded, tarped, 12" depth before bed-forming	23	139	108 [b]	187	447
	FL 2000	Bedded, tarped, 12" depth before bed-forming	20	149	107 [b]	636 [c]	1417
Petty (2001)	Brawley, CA 1991	Not specified beyond soil injection	15	118	100	39	110
	Chualar, CA 1991	Not specified beyond soil injection	10	121	100	27	74
	Firebaugh, CA 1993	Not specified beyond soil injection	10	124	100	69	185

a Air concentration adjusted proportionally for maximum permitted rate of 332 lbs/ac.
b Only distance at which air was monitored.
c Measured 24-hr concentrations at 107 ft were $\geq$ 250 $\mu g\ m^{-3}$ on 4 consecutive days.

References

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Rotondaro, A. 2001. 1,3-dichloropropene exposure to workers tarping beds during pre-bed fumigation with 1,3-d soil fumigants. Fresno, CA: Paragon Research Services. (DPR Doc. No. 50046-173, Record No. 181608)

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cc: Ruby Reed, Medical Toxicology Branch
Bruce Johnson, Environmental Monitoring Branch