Health Canada / Santé Canada
Pest Management Regulatory Agency / Agence de réglementation de la lutte antiparasitaire

Date Received - Date de réception : 2009-03-13
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Notice of Objection to a Registration Decision under Subsection 35(1) of the *Pest Control Products Act*

Avis d'opposition à une décision d'homologation en vertu du paragraphe 35(1) de la *Loi sur les produits antiparasitaires*

1. Objector information - Information sur l'opposant

Name - Nom / Corporation - société / Organization - organisation: Michael Keim			
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2. Product information - Information sur le produit

Name of active ingredient to which the decision relates:
Nom de la matière active à laquelle la décision se rapporte : Chlorpropham

Name of end-use product to which the decision relates:
Nom de la préparation commerciale à laquelle la décision se rapporte :

3. Registration decision to which the objection relates - Décision d'homologation pour laquelle vous déposez un avis d'opposition

Decisions on application - Décision concernant la demande

- ☐ Granting registration - Homologation accordée
- ☐ Denying registration - Homologation rejetée
- ☐ Granting an amendment of a registration - Modification à l'homologation accordée
- ☐ Denying an amendment of a registration - Modification à l'homologation rejetée

Decisions on re-evaluation or special review - Décision concernant la réévaluation ou l'examen spécial

- ☑ Confirming registration - Homologation confirmée
- ☐ Cancelling registration - Homologation annulée
- ☑ Amending registration - Modification à une homologation

4. Date the decision statement was made public: Date de la publication de l'énoncé de décision : Unknown but after 1/19/09

5. Area of scientific evaluation to which the objection relates - Volet de l'évaluation scientifique touché par l'avis d'opposition

- ☑ Health risk assessment (toxicology, food residue, occupational exposure) - Évaluation des risques pour la santé (toxicologie, résidus dans les aliments, exposition professionnelle)
- ☑ Environmental risk assessment (environmental fate, environmental toxicology) - Évaluation des risques pour l'environnement (devenir dans l'environnement, écotoxicologie)
- ☐ Value and efficacy assessments (crop tolerance, value) - Évaluation de la valeur et de l'efficacité (tolérance des cultures, valeur)

6. Scientific basis for the objection / Fondement scientifique de l'opposition
Attachment included: / Pièce jointe incluse : ☑ Yes / Oui ☐ No / Non

Please see attachment

7. Signature of objector or representative - Signature de l'opposant ou de son représentant

Michael I Keim
Printed Name - Nom en lettres moulées

Objectors who submit confidential information (i.e., confidential business information, confidential test data) are responsible for identifying this information which is part of their submission.

Information required to process the notice of objection may include some personal information as defined in the *Privacy Act*. In accordance with that Act, such personal information may be made public as authorized by the *Pest Control Products Act* and its regulations. Under the *Privacy Act*, individuals have the right to look at their personal information. For more information on how PMRA manages personal information, contact the PMRA Information Services at 1-800-267-6315 within Canada and 1-613-736-3799 outside of Canada or via e-mail at pmra_infoserv@hc-sc.gc.ca.

Les opposants qui soumettent des renseignements confidentiels (c.-à-d. des renseignements commerciaux confidentiels, des données d'essai confidentielles) sont responsables de les désigner comme tels dans leur envoi.

L'information requise pour traiter cet avis d'opposition peut comprendre certains renseignements personnels tels que définis dans la *Loi sur la protection des renseignements personnels*. Conformément à cette Loi, ces renseignements peuvent être rendus publics, ce qui est permis par la *Loi sur les produits antiparasitaires* et son Règlement. En vertu de la *Loi sur la protection des renseignements personnels*, tous les individus ont le droit de consulter leurs renseignements personnels. On peut obtenir des précisions sur la gestion des renseignements personnels auprès de l'Agence de réglementation de la lutte antiparasitaire (ARLA) en communiquant avec le Service de renseignements au 1-800-267-6315 au Canada, ou au 1-613-736-3799 de l'extérieur du Canada, ou par courrier électronique à pmra_infoserv@hc-sc.gc.ca.

Canada

Attachment to Notice of Objection to a Registration

March 12, 2009

Re-evaluation Decision Chlorpropham RVD2008-01

The aerosol application of chlorpropham (CIPC) is unique. The application science is much different than the science used with other pesticides and therefore little if any organized guidance is available from academic sources. This gap needs to be filled in order to insure efficacy for CIPC use and assure human and environmental health and safety. Additional data is required as part of this re-registration. The proposed label needs to be improved to control the hazards of CIPC use and assure public health and safety.

We will try again to discuss the reasonable facts of the CIPC application with you. Keep in mind that we were the main initiators of the CIPC aerosol application science in practice today. It would seem that you might actually listen to the people that essentially **INVENTED TODAY'S CIPC AEROSOL APPLICATION SCIENCE**. Also, this process has taken over two years to go through and still isn't over. We could have dealt with the entire situation within a matter of weeks had you ever contacted us after our first communication. This leads one to question if PMRA doesn't care when the assessment gets finished or whether or not they understand it or whether or not the population is protected.

We noted that you did not answer most of the questions (or concerns) we raised. With respect to those questions you didn't answer we accept that you accept them as factual. Your lack of response to our questions means that you allow or condone the given issue.

We have taken the liberty to highlight in red your exact words from your response to our Notice of Objection for the ease of clarity. We have also taken the liberty to use "**bold**" terms where we believe extra focus needs to be applied. We respectfully request that you answer all questions raised herein.

Objectors Comments on PMRA Appendix I Comments and Responses

2.0 Comments on Atmospheric Release of Chlorpropham

For sake of clarity these are the questions we asked in our last NOO in this section:

1. **Has anyone at PMRA actually seen a commercial aerosol application of CIPC to stored potatoes? What were the treatment parameters and what was observed?**

2. **If not up to a 50% CIPC loss during aerosol treatment, then what is the acceptable percentage loss of CIPC to the environment during the application process? 20%? 30%? How did you determine this percentage loss of CIPC to the environment?**

Background for these questions (from our previous correspondences) is as follows:

The mass balance for chlorpropham aerosol application was significantly improved by the new application technology introduced during the 1980s (by Bill Keim) but remains very, very poor to the present day. The improvement in the 1980s was due to the use of a high assay formulation and the control of aerosol handling. The 1980s changes provided very significant reduction in the displacement when compared to the 1960s and 1970s technology which typically gave residues on the potatoes of 3 to 15 % of the product applied (Representative data is reported in ASTM Formulation Paper Table 1 for work done in 1982.). Now there is opportunity for an additional displacement improvement.

The assumption that "some particles would accumulate on the building surfaces (as demonstrated by the need to regularly clean fans, plenums, etc.)" is evidence of using old application "art" and was addressed and resolved in the 1980s technology on which information was provided earlier. Application improvements in aerosol handling essentially eliminated the need for the cleaning of the fans and building surfaces necessary when using old "art". Failure to eliminate these deposits indicates that the chlorpropham deposit on the potatoes will not be uniform. **Uniformity is essential to the use of residue measurements for the toxicological assessment.** In particular, much higher deposits in the bottom of the pile are to be expected because of excessive coagulation of aerosol particles due to poor handling of the aerosol in the potato storage air (Please see scientific information in SPROUT NIP AEROSOL APPLICATION FIELD HANDBOOK available from Brenntag).

In our experience, almost all potato samples from potato storages for residue determination are taken from about 12 to 18 inches below the top surface of the pile. If the residue values from near the top of the pile are not representative of the pile, then fixing the mass balance without significant displacement means that the amounts present lower in the pile are orders of magnitude higher.

Control of aerosol application variables makes a fairly uniform application from bottom to top of the potato pile possible. The presence of the aerosol for an hour or more after the end of the actual introduction of aerosol is an indication of a uniform treatment. For typical potato storages, a reasonable aerosol introduction time can be expected to be from a half to one hour. A diffusion controlled aerosol application process is required for uniform deposition. The correct implementation of the 1980s technology changes fixed significant factors associated with the old art and resulted in an increase in the improvement of the diffusion deposition mechanism. If visible solid deposits are present, then this indicates that much larger particles were formed early in the application process with a severe loss of the diffusion mechanism needed for uniform CIPC application. When the diffusion mechanism is lost, the ability to evenly control the uniform

deposition of CIPC onto the potato pile is lost and creates significant concern for the measurement of residue levels on the potatoes by current practice.

Continuing with assumption "and some would be broken down and destroyed during the typical application and ventilation practices", comments concerning this factor were provided earlier. During a field visit to potato storages in February of 1988 in Canada, when 1980s technology was being taught to applicator, a sample of residue was obtained from a fan shroud. This sample contained about 10 % of N, N'-di-(3-chlorophenyl)-urea. Assuming 100 % conversion (50% is probably a better estimate) during the decomposition about 15 % of chlorpropham was broken down. Applicators were reminded of prior instructions not to exceed 1100 °F in the aerosol generation process (the operators had purposefully exceeded this temperature in this application). Comment was made in response to PACR2007-04 to put aerosol generator operating information on the label.

Once the above factors are under control then the engineering analysis provided in the ASTM published paper on Application can be applied. The potato storage surface area of a "bad case" potato storage was estimated and found to be about 20 % of the surface area of the potatoes contained in the storage. With application and storage factors under control, the amounts on the storage surfaces can be estimated from potato residue assays. This engineering analysis provided estimates for the amounts of chlorpropham that were not lost to the atmosphere from use of the high assay formulation, Sprout Nip 7A, compared to the old low assay 4A formulation when using proper aerosol generator operation and control of important potato storage application factors. The high assay 7A formulation was created in order to significantly increase the uniformity of deposition of CIPC and, most importantly, increase the amount deposited on the potatoes. The use of the solid chlorpropham formulation can also be estimated using the published ASTM papers just as it was used in the 1980s to improve the CIPC application with respect to the 7A formulation.

It is useful to look at the estimated losses for a 2x application compared to two 1x applications when the visible aerosol is allowed to be deposited on the potatoes between the two 1x applications. The engineering analysis shows that losses for the 2x treatment are far greater than the losses from two 1x treatments when the aerosol was allowed time to deposit on the potatoes between the two 1x treatments. What we mean by this is that the 2x treatment in Canada displaces far more CIPC to the environment than the use of two separated 1x treatments (See Table 3 of "Application of an Aerosol Formulation to Potato Storages"). We think this adequately explains why process improvements still need to be made. **We don't mean to be intrusive, but does PMRA understand this rationale?** We ask this question because it is very important to understanding why changes were made to the CIPC application process in the 1980's and why there should be further changes implemented now.

We believe that new CIPC aerosol application technology using potato storage air for the aerosol generation will offer improvements at least equal to those made by PPG in the 1980's with respect to aerosol formulation and aerosol handling.

We believe that a reasonable assessment of above evidence and questions answered by the technology referenced shows that the up to 50 % loss of chlorpropham is reasonable by the 1980s technology. **If not up to a 50% loss, then what is the acceptable percentage loss of CIPC to the environment during the application process? 20%? 30%? How did you determine this percentage loss of CIPC to the environment?**

Because aerosol applications resulting in significant elimination of this large atmospheric loss of CIPC have started, we again state that more data requirements are needed for application processes using potato storage air as part of aerosol generation in order to accurately control the residues that result. Residues by this improved process will be higher.

Here is your response verbatim (in red below) along with our comments pertaining to your most recent response for this NOO.

Your first sentence is:

"No monitoring data exists to support the release of chlorpropham to the atmosphere nor to confirm the deposition on surfaces within the facility."

Our comments:

Your remark of "no monitoring data exists" tells us that not one person, ever, from PMRA, has seen an actual application of CIPC to a potato storage. No one in industry is actually interested in obtaining this type of data with respect to the CIPC aerosol application because it would raise red flags with the regulatory people and would be very costly (this is partly because of the effects of large variability in the construction of the potato storage). Label holders do not wish to document a serious fault or flaw with the CIPC aerosol application in order to avoid any registration issues. However, as explained below, a reasonable engineering analysis of the CIPC aerosol application (factors in all important parameters under the conditions necessary for good uniform deposition of CIPC onto the potatoes) is published in a respected peer reviewed publication and available for use.

It is wrong of your agency to tell the public that you are protecting them and you have never seen what you are evaluating. **Do you not see a problem with this?** I would like to point out, right now, that the PMRA's position, according to the above comment, is that up to 50% CIPC can be lost to the atmosphere and it is not a problem.

The first sentence also states that there is nothing to confirm deposition on the surfaces of the storage during CIPC treatment. We are assuming that any visible deposition is essentially eliminated and the focus is on diffusion deposition. There is a large amount of data available relating to the CIPC residues on the potato surfaces by diffusion deposition. The potato surfaces are, by far, the largest surface area present in the potato storage for making a diffusion deposition of CIPC that is required for efficacy. The

potato residue data can be used to estimate diffusion deposition on the other potato storage surfaces. Previously, we have suggested that a reasonable value for the amount of CIPC on other surfaces of a typical potato storage is about 20% of the amount that is found on the potatoes provided the application takes place primarily by a diffusion mechanism.

It should also be pointed out that your label holders have known about this CIPC displacement loss since they first got into the business. They have known about the vast quantities of CIPC going into the environment ever since they got into the business as it has been going on forever. They have avoided addressing this issue.

Most importantly, you have no data supporting that vast amounts of CIPC <u>are not</u> lost to the environment.

Your 2nd paragraph states:

"Although indications are that less than 50% of the applied chlorpropham is deposited onto the potato pile, there is no evidence to suggest that as much as 50% is lost to the atmosphere. It is assumed that some particles would accumulate on the building surfaces (as demonstrated by the need to regularly clean fans, plenums, etc.) and some would be broken down or destroyed during the typical application and ventilation practices. Of the remaining chlorpropham, ventilation to the outside atmosphere would obviously dilute the concentration of suspended chlorpropham particles considerably. No health effect incident reports were found in either the U.S. or Canada related to occupational or bystander chlorpropham exposure."

Our comments to your 2nd paragraph:

In your first sentence of your second paragraph you state, "Although indications are that less than 50% of the applied chlorpropham is deposited onto the potato pile". Thank you for recognizing the fact that the current aerosol application process for CIPC puts onto the potatoes less than 50% of what is put into the storage building. It is the first step in identifying the truth about this aerosol application process.

In your second sentence, second paragraph you state, "It is assumed that some particles would accumulate on the building surfaces (as demonstrated by the need to regularly clean fans, plenums, etc.) and some would be broken down or destroyed during the typical application and ventilation practices."

The assumption that "some particles would accumulate on the building surfaces (as demonstrated by the need to regularly clean fans, plenums, etc.)" is evidence of using old application "art" from the 1960's and was resolved with the 1980s technology Bill Keim introduced. Bill's application improvements in aerosol handling essentially eliminated the need for the cleaning of the fans and building **<u>surfaces</u>** that was necessary when using the prior old "art". One still may want to clean the fan blades though as there may be <u>minor</u> visible accumulation present there. Unless the given storage building is still

running all of its internal fans at high-speed (which they aren't or the treatment would not work very well if at all) surface accumulation will essentially be nonexistent. **Failure to eliminate visible surface deposits indicates that the chlorpropham deposition on the potatoes will not be uniform.** In particular, much higher deposits in the bottom of the pile (probably exceeding the MRL and especially occurring when using high assay formulations) are to be expected because of excessive coagulation of aerosol particles due to poor handling of the aerosol in the potato storage air (Please see scientific information in SPROUT NIP AEROSOL APPLICATION FIELD HANDBOOK, written by Bill Keim, available from Brenntag or us).

The continuation of the second sentence, "and some would be broken down or destroyed during the typical application and ventilation practices" is very interesting. **You now have brought forth and recognize the concept of chemical degradation of the CIPC in the aerosol application process. New toxicological data is required for the potentially large amounts of CIPC degradation products that are being applied to the potatoes that are to be consumed by humans because none of the suggested controls on the CIPC aerosol application process are part of your response.** We are aware of a fan shroud residue from a Canadian potato storage that contained a large amount of the urea impurity. **Alternately, reasonable CIPC aerosol generation guidance can be put on the label to control CIPC degradation.**

With respect to how much is vented to the atmosphere after no visible aerosol remains in the post-CIPC application ventilation process, this number is very small. Supporting data for vapor concentration of CIPC present in the storage is available from the United Kingdom, as they have done extensive work in this area. Almost all of the displacement of CIPC occurs during the CIPC introduction phase of the treatment, not the venting of the residue at the end of the treatment.

It now would make sense to use a reasonable engineering analysis to explain what is happening in a good CIPC application process. We will use a modified mass balance formula that we gave to you previously in Bill Keim's CIPC Application paper published by the ASTM in 1996 (note V has been changed to represent PMRA vented CIPC and S is the V, visible CIPC, in the paper). The variables in the formula as identified by PMRA and us are:

B – Amount of CIPC used during application

V – Amount of CIPC Vented when no visible aerosol is left inside building

I – Amount of CIPC vented to atmosphere during CIPC introduction phase

P – Amount of CIPC vented to atmosphere after CIPC introduction phase

R – Total amount of CIPC deposited upon the potato pile

S - Amount of CIPC accumulated upon internal surfaces.

Now let us look at a Mass Balance for the CIPC used in an application and see if we can approximate the amount lost to the environment. A mass balance is basically what goes into the process equals what comes out of the process.

$I + P = B - V - R - S$

Now lets identify some facts.

1. For a good potato storage which has no leakage the amount of CIPC vented to the atmosphere after CIPC introduction phase is zero, P = 0. For a storage with leakage the maximum amount vented can be estimated.
2. When venting occurs, no visible aerosol is left therefore much less than 1% of the CIPC is present in the air, thus we will say V=0.
3. Since all good applications of CIPC now use the low internal storage fan speed concept to control turbulence, surface accumulation is estimated to be about 5% for many storages, thus S = 0.05B. The non-potato surface area of the storages has been estimated to be about 20% of the total the surface area that is available for diffusion deposition in a typical storage.
4. PMRA acknowledges that less than 50% of the CIPC applied to the storage is deposited upon the potato pile R < 0.50B. Let us assume that 50% of the applied amount of CIPC makes it to the potatoes (50% of "B", the amount put into the storage for treatment. It should be noted that this 50% assumption is a best-case scenario).

Our Mass balance for CIPC used in a treatment is:

$I + 0 = B - 0 - (0.50B) - 0.05B$

Leads us to:

$I = 0.45B$

We know that this simple but reasonably accurate mass balance shows that **in a best case scenario 45% of the CIPC applied to a potato storage for treatment is lost to the atmosphere**.

An equation is available that allows potato storage building parameters along with application variables to estimate the maximum amount that is lost to the atmosphere for a given potato storage and aerosol application.

Your last sentence, second paragraph states: "No health effect incident reports were found in either the U.S. or Canada related to occupational or bystander chlorpropham exposure".

Our comments to this are: We supplied you with an example of CIPC poisoning prior to you writing this document. The case was in Maine, USA, just south of your border with the USA. Did you fail to read it? Most cases regarding CIPC will have sealed court records so the company can hide what it has done. If you contact the attorney of record on the case we supplied you with, he will tell you that the CIPC applicator had to write a $250,000 check to settle the case. If no harm can be done then why did they pay off the case? If no injury was done, then why pay $250,000? It begs us to wonder how many health incident reports get filed when the person that is aggrieved gets a fat check to compensate them and they aren't allowed to speak about it as a condition of the settlement?

In your third paragraphs you state, "Both long-term storage facilities using aerosol foggers and smaller facilities using liquid spray conveyor belts were assessed by the PMRA. Those workers in the smaller facility incur more exposure than any other individuals associated with the application of chlorpropham to storage potatoes". Again this statement shows your understanding of how CIPC can be absorbed by humans is misguided. You state that the workers in the smaller facilities using conveyor belts get more exposure. This statement is untrue. Exposure by the worker in the smaller facility (using the conveyor belt and spray applying CIPC) has controls to limit the workers ability to be exposed to CIPC. These controls are not in place to protect the public or the applicator with respect to the aerosol CIPC application because of a "no significant CIPC aerosol loss to the environment assessment by PMRA". Furthermore, the particle size of CIPC that the packaging house worker is exposed to is much too large to be taken into the lungs and ventilation control **is required** for the packaging house worker. It will be trapped in the nose at best, but probably will be too heavy to ride in the air in order to even get to the nose. The CIPC aerosol is totally different. The aerosol particle is small enough that it readily rides the air and passes through the nose and is put into the lungs. This CIPC aerosol particle size is acknowledged as less than 5 microns and this size is readily absorbable by the lungs.

Your fourth paragraph we have no comment on.

Your fifth paragraph states, "Given that the amount of chlorpropham that is displaced to the atmosphere is likely to be considerably less than 50% of the label rate, that any chlorpropham particles available to respiration/dermal contact would be greatly diluted by the atmosphere, and that the risk assessment for occupational workers does not exceed the Agency's level of concern (8 hours/day at the maximum label rate), it is highly unlikely that any incidental bystander exposure would be of concern to the Agency. Following any application, the remaining chlorpropham that is released to the atmosphere and thus diluted would result in far less exposure than that incurred by storage facility workers. No further residential risk assessment is required to assess chlorpropham exposure to individuals within the vicinity of the facilities".

When laying out the grounds for a rationale, one begins by stating the variables that they will assume a value for in their arguments. Our concern for your scenario is that it doesn't address the incidental bystander, of significant risk, that is exposed to large

amounts of CIPC that are released in a relatively short time from potato storages located in residential areas (a lot of treated storages are in residential areas). Please see United Kingdom article for treated people living near a potato storage.

Because an improved aerosol application process for elimination of this large atmospheric loss of CIPC has started by Brenntag in Canada, we again state that more data requirements are needed for this aerosol application process using potato storage air as parts of aerosol generation in order to accurately know what are the residues that result.

4.0 Comment on Application rate differences

We did not state that the Canadian application rate was double that of the USA. We said that some treatments in Canada are made at two times the normal application rate. This will lead to a marked increase in the amount of CIPC lost to the environment. A 2x treatment is comprised of two CIPC aerosol treatments each using 100% of the label rate and made in a continuous manner. A 1x treatment is a CIPC aerosol treatment made at the normal label rate. This displacement rate change is not a concern for an occupational worker who knows to stay out of visible aerosol but that of the concern for an incidental bystander that is a resident near a potato storage. The example discussed in the background of our response concerning the "1x" and "2x" treatments was used to identify the amount of CIPC vented to the atmosphere (using the engineering model for CIPC in the aerosol treatment) and that the "2x" treatment had significantly larger losses of CIPC to the environment than the "1x" treatment. The solution to controlling some of this displacement loss (this rationale only applies to two treatments of CIPC aerosol made in a continuous manner) is to allow the CIPC aerosol to settle in the storage prior to starting the second treatment.

Items Ignored by PMRA Re-registration Decision Response that need to be answered.

Below is a list of concerns along with a brief rationale:

1. An internal air recirculation system is needed for the potato storage to assure reasonably uniform deposition of chlorpropham in order to obtain reasonable residue data. A suitable statement needs to be put on the label. Without this air recirculation system there will not be uniform deposition on the potato pile and therefore the residue levels will be grossly misrepresented. **Why is uniform deposition of CIPC on the potato pile not critical to determining human exposure? If deposition is not uniform your sampling criteria used to check residue levels is wrong and does not truly represent the residue of CIPC on the potato pile.**
2. No guidance is provided on the label for minimizing air turbulence in the potato storage internal air re-circulation system. This is necessary to get the uniform

deposition of the chlorpropham and uniform residues. **What are the reasons that this guidance is not needed on the label?**

3. No guidance is presented on the label for the maximum amount of chlorpropham formulation in the air that is processed by the aerosol generator to help prevent fire and explosion in potato storage. This omission creates serious risk for the operator and other people nearby. **With fires in potato storages occurring on a regular basis and the fact that this guidance was on earlier labels, why is this guidance on fire and explosion risk not needed?**
4. Degradation of chlorpropham by high temperature both in thermal aerosol generation and in the use of the melted solid chlorpropham formulation as it effects treatment and risk assessment is not addressed by engineering controls on the product label. The issue of degradation was raised by PMRA to account for chlorpropham in the mass balance for the application process. **PMRA has admitted that CIPC degradation occurs. What amount of degradation is acceptable? 10 %? Please show us and explain your assessment rationale (including the list of CIPC chemical degradates for which you analyzed) for the toxicity data generated to support allowing this amount of CIPC degradation and how you reached the conclusion that it is not harmful to humans.** When the operator melts the CIPC, operator exposure increases (CIPC aerosol has been observed forming inside a truck housing from the vapors escaping from a melting tank). **Why has PMRA not performed a risk assessment with respect to the use of the solid CIPC and operator exposure? How much CIPC degradation is acceptable in the melting and use of melted material part(s) of the process? What total amount of degradation is acceptable?**
5. Potato size variation effect on potato sampling for residue assay is not minimized for residue determination (PPG initiated a procedure for measuring the size of the potatoes (using their individual weights) in the sample that was analyzed in about 1986). One needs to pay close attention to the size of the potatoes that are taken for residue determination. Small potatoes result in very high assays. Large potatoes result in very low assays. **Does PMRA take into account this variation of potato sizes in its determinations when calculating the residue levels and MRL's? Why is this significant variable not important to determining the MRL? Again, if deposition on the pile is not uniform, your CIPC MRL measurements are flawed and not representative.**
6. Control of tank mixing of chlorpropham with other chemicals for aerosol application is necessary for operator safety and is not on the product label. In the US during 2006, clove oil, a sprout inhibitor, was tank mixed with CIPC and a total potato loss fire occurred at the storage. This fire was a direct result of the applicator not understanding the parameters of what he was using. **Why is this unique nature of use not addressed on the CIPC label so as to insure human health and safety? Have the necessary chemical stability and toxicological tests been performed to evaluate this combining of chemicals at elevated temperature?**
7. In Canada, you currently have two different ways of applying CIPC to a potato storage. One involves the excessive loss of CIPC to the environment. The other

involves the loss of maybe only 10-15% of the CIPC lost to the environment. Both application techniques are only in use by Brenntag. The rest use the technique that loses vast amounts to the environment. These two procedures will yield two entirely different residue levels. **This can lead to a much larger concentration of CIPC (using the reduced CIPC loss to the environment procedure) and its degradation products on the potatoes. Have residue data been used with the toxicological data supporting this exposure to humans and the environment?**

8. **Why has this displacement issue not been brought to the attention of the PMRA prior to our involvement?** The large amounts of CIPC being put into the environment has been going on since they started aerosol CIPC treatments. We are pursuing this because you are not protecting the citizens of your country and thereby you are not protecting the citizens of our country, the USA. **You have allowed displacement to go on this way since PMRA began to register chemicals and we can no longer allow you to continue this path of negligence without trying to show you and the general public the facts for the aerosol application.**
9. Guidance for the amount of formulation or the amount of chlorpropham in the aerosol stream was previously provided to all applicators for the application of liquid chlorpropham formulation, Sprout Nip 7A. PPG Industries put such data on the label to reinforce the policy and to mitigate the risks for fire and explosions during the treatment. Potential wording is: "The aerosol generator shall be operated so that the concentration of chlorpropham or the formulation of chlorpropham and other chemical(s) in the air stream from the aerosol generator shall not exceed _____". The "blank" is filled in with an amount of the formulation with respect to the amount of air for the product to which the label applies. Lower flammable limit and autoignition temperature data from recognized standard tests can be used in the determination of the value to be put on the label. **This will help to try to make sure fires don't happen.**
10. Based upon PPG Industries comprehensive testing program and experience with the thermal aerosol generating process, PPG imposed a maximum temperature to be used in the aerosol generation process to insure adequate safety measures. PPG/StanChem supplied this guidance to all applicators. PPG knew that large amounts of chemical degradation occur at the higher temperatures and that this factor can be expected to be a serious problem for the applicators with regards to human health concerns. Suggested wording for present aerosol generation process is: "The maximum temperature that contacts chlorpropham at any point in the thermal aerosol generation process shall not exceed 593 °C (1100 °F). Even at this temperature chemical degradation of CIPC occurs. This needs to be addressed because a potential CIPC degradation by-product (there are others) is 3-chloroaniline. 4-chloroaniline is a known potential carcinogen which leads one to ask about the potential for 3-chloroaniline to be a carcinogen.
11. As we mentioned earlier, fire and explosion hazards have a high potential to occur during the chlorpropham application process. This is of serious concern when just chlorpropham is used in the application but some applicators have begun to add other chemicals (potential sprout inhibitors, e.g. clove oil, etc.) to the mix

used in the application. A problem is that a US Clove Oil product label claims that their product is exempt from USEPA regulation. The US clove oil product and the chlorpropham were tank mixed and applied to a potato storage in the USA and a large fire occurred. **This is of real concern since the explosion and fire risks are not known when these chemicals are mixed.** Suggested wording is: "Chlorpropham shall not be tank mixed for application with other chemicals for which the fire and explosion parameters are not known. The product label for any chemical that is tank mixed with chlorpropham shall clearly define the conditions and hazard controls needed for the tank mix use in aerosol generation.

12. PPG Industries performed studies on melted solid chlorpropham. Based upon the Sprout NIP 7A label, the suggested wording is: "Temperature of the melted solid chlorpropham that is used for aerosol generation shall be kept at 60°C (140 °F) or below". The use of higher temperature is known to us and is cause for concern because of dramatically increased CIPC degradation issues.
13. The new application technology effectively controls the displacement losses of chlorpropham to the environment. Brenntag has a machine that has successfully performed this new technology application and it has been in use since 2004. Elimination of the displacement losses of chlorpropham is the major concern regarding controlling the negative human and environmental health issues pertaining to the chlorpropham treatment process. Suggested wording is: "The aerosol generator shall use a minimum of 80% of the total air used for the external part of an aerosol generation process from the storage (versus all ambient or external air) in order to control the displacement losses of chlorpropham from the storage into the environment". This technology is much preferred as it minimizes the effect of a number of potato storage factors on the aerosol application. This is non-patented technology in your country. Additional data requirements for increased residues on the potatoes by the new process are needed as part of continued registration.

Health Risks of CIPC that must be addressed by PMRA

We are concerned about your statement "No health effect incident reports were found either in the US or Canada related to occupational health or bystander chlorpropham exposure". By using Google we found two items in a simple non-exhaustive search that can be of interest. We supplied these articles to you prior to your writing this document.

The first article was for an exposure in Maine and concerns the exposure of two workers at a storage facility that was being treated with CIPC aerosol. The workers were awarded a cash settlement. This incident shows that displacement to the atmosphere includes other interior parts of a building when a bin that is part of the building is being treated.

The second article is for the continuing exposure for a UK family that lives next door to a potato storage facility that is treated with chlorpropham.

Does the PMRA not believe that by reducing human exposure to CIPC by eliminating CIPC aerosol displacement it will significantly lower the exposure risk?

CIPC is also known as a pseudo cholinesterase inhibitor. Pseudo cholinesterase inhibitors are of very serious concern for people that are especially sensitive. It also has other negative impacts for which we refer you to the World Health Organization.

Closing:

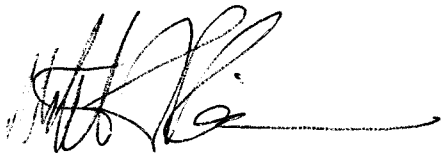
Everything PMRA has discussed to date assumes one thing and that is that all storages are equal. This is far from the truth. Storages vary in shape, size, capacity, age, leakage etc. Bottom line is that the older storages tend to have more leakage and will vent even more CIPC to the atmosphere. These older storages are also the storages that tend to be located in residential areas

We are trying our best to help you understand the CIPC application process but can't understand why you are fighting so hard to accept a reasonable explanation of the aerosol application process.

As people who are responsible for assessing CIPC application, your lack of understanding of the CIPC process you are supposed to be regulating is a matter of grave concern. What is amazing is that you try to fight science (reasonable analysis) with non-science (make believe).

We respectfully suggest that you hire some outside experts to help you with this registration. There are qualified people available that can help you. If you don't, then one will be able to safely assume whatever registration for CIPC you approve for your country will be inadequate.

Regards,



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