

[REDACTED]

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**From:** BROECKAERT Fabrice  
**Sent:** 13 June 2016 15:34  
**To:** [REDACTED]@ecpa.eu  
**Cc:** [REDACTED] ECHA Classification; ECHA  
Committee Risk Assessment; KARHU Elina; [REDACTED]  
**Subject:** Follow-up on pinoxaden: Resp Irrit./Sens.  
**Attachments:** Syngenta\_Pinoxaden workers effects vs CLP\_13062016.docx

**Follow Up Flag:** Follow up  
**Flag Status:** Completed

Dear [REDACTED]

As you know, during the RAC-37 plenary discussion some RAC Members did not exclude a classification of pinoxaden as a respiratory sensitiser while others expressed the view that the available data are currently insufficient for a classification (due to e.g. absence of objective measurements). Further clarification on the human data were requested from the industry representative and the decision on this hazard class is postponed to the next plenary meeting in September.

Could you please forward the attached document to Syngenta as soon as possible? RAC and ECHA secretariat would greatly appreciate responses to questions and clarifications preferably no later than **1 July 2016**.

Thank you in advance.

Kind regards,  
Fabrice

## Pinoxaden worker's health effects: request for additional clarifications

### Introduction

To whom it may concern.

RAC and ECHA secretariat would greatly appreciate additional responses to questions and clarifications as soon as possible, preferably no later than **1 July 2016**.

In addition to specific questions presented below (under CLP criteria), the rapporteur would like industry to further:

1. Clarify why the 3 cases of "asthma like symptoms" were identified as such and what made these 3 cases different from the other cases of respiratory irritation. It would also be good to know whether the confirmed case of occupational asthma was one of these 3 cases and
2. Provide detailed information on the effects observed in those employees affected before 2010. In the document "Syngenta response to questions from ECHA on pinoxaden" industry provided detailed information on all cases between 2010 & 2013, if available it would be useful to get this information for the cases before 2010 as well.

### CLP Criteria for Respiratory sensitisation and questions to industry

#### Annex I: 3.4.2.1.2 Human evidence

**Annex I: 3.4.2.1.2.1.** *Evidence that a substance can lead to specific hypersensitivity will normally be based on human experience. In this context, hypersensitivity is normally seen as asthma, but other hypersensitivity reactions such as rhinitis/conjunctivitis and alveolitis are also considered. The condition will have the clinical character of an allergic reaction. However, immunological mechanisms do not have to be demonstrated.*

- ⇒ Do you consider that the reactions observed in workers and the 7 cadets<sup>1</sup> constitute "other hypersensitivity reactions" than e.g. asthma?
- ⇒ Were you aware of the reported incident related to 45 cadets crawling through a field that had been treated previously with pinoxaden. Seven of the cadets reported wheeze, facial swelling and swelling of the throat, although no skin reactions were reported. Were you contacted by the UK National Poisons Information Service (NPIS) or any other bodies for a follow-up of the incidents? Do you have additional information?
- ⇒ Do you consider the following symptoms to have the clinical character of an allergic reaction? Those were reported in both workers in cadets.
  - Cough
  - Sneeze

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<sup>1</sup> <https://cot.food.gov.uk/sites/default/files/TOX2015-30%20FOLLOW-UP%20PAPER%20on%20skin%20sensitisation%20-%20format.pdf>

- Wheeze
- Short breath
- Lung congestion
- Red/swollen eyes, facial swelling
- Itchiness (red skin and itchy on wrists)
- Swelling of the throat

⇒ Did the use of an “inhaler” reduce the symptoms?

**Annex I: 3.4.2.1.2.2.** *When considering the human evidence, it is necessary for a decision on classification to take into account, in addition to the evidence from the cases:*

*(a) the size of the population exposed*

- ⇒ What is exact number of workers exposed vs. the number of workers affected? Please provide the number in a single table, per location and years, summing up the total number exposed vs. affected.<sup>2</sup>
- ⇒ What is the prevalence of asthmatics in the UK population around 2010-2013?

*(b) the extent of exposure*

- ⇒ Is data on ambient air monitoring of pinoxaden available (before 2010, for the period 2010-2013 and after 2013)?
- ⇒ What is the average duration of the possible exposure (before 2010, between 2010-2013 and after 2013)

**Annex I: 3.4.2.1.2.3.** *The evidence referred to above could be:*

*(a) clinical history and data from appropriate lung function tests related to exposure to the substance, confirmed by other supportive evidence which may include:*

- (i) in vivo immunological test (e.g. skin prick test)*
- (ii) in vitro immunological test (e.g. serological analysis);*
- (iii) studies that indicate other specific hypersensitivity reactions where immunological mechanisms of action have not been proven, e.g. repeated low-level irritation, pharmacologically mediated effects;*

- ⇒ Our understanding is that none of the above information is available,- please confirm

*(iv) a chemical structure related to substances known to cause respiratory hypersensitivity;*

- ⇒ QSAR analysis: the full DEREK report shows that there is an alert for skin sensitisation, but not respiratory sensitisation

*(b) data from one or more positive bronchial challenge tests with the substance conducted according to accepted guidelines for the determination of a specific hypersensitivity reaction.*

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<sup>2</sup> Some of this information was already provided by industry, however, we would need a clarification why in some cases the number of affected individuals is compared to 306 employees exposed, but in others to 315 or to approximately 330.

- ⇒ Our understanding is that none of the above information is available,- please confirm

**Annex I: 3.4.2.1.2.4.** *Clinical history shall include both medical and occupational history to determine a relationship between exposure to a specific substance and development of respiratory hypersensitivity. Relevant information includes aggravating factors both in the home and workplace, the onset and progress of the disease, family history and medical history of the patient in question. The medical history shall also include a note of other allergic or airway disorders from childhood, and smoking history.*

*(a) smoking history and/or allergic history of the workers*

- ⇒ Is this information available? If yes, please provide it.

*(b) aggravating factors attributable and available for the workers?*

- ⇒ Is this information available? If yes, please provide it.

*(c) family history of the patient*

- ⇒ Is this information available? If yes, please provide it.

*(d) follow-up (medical history) of the workers who has left the plant/work place available?*

- ⇒ Is this information available? If yes, please provide it.

[REDACTED]

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**From:** [REDACTED]@ecpa.eu>  
**Sent:** 13 June 2016 18:19  
**To:** BROECKAERT Fabrice  
**Subject:** Re: Follow-up on pinoxaden: Resp Irrit./Sens.

Hi Fabrice, yes I'll pass onto [REDACTED]. Any feedback from your telecom with Efsa and the templates. Likewise interesting comment from [REDACTED] and his preference for open text and discussion rather than a template.  
Best regards  
[REDACTED]

Sent from my iPad

On 13 Jun 2016, at 13:34, BROECKAERT Fabrice  
<Fabrice.BROECKAERT@echa.europa.eu<mailto:Fabrice.BROECKAERT@echa.europa.eu>> wrote:

Dear [REDACTED],

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