[redacted]

From: [redacted]@ecpa.eu>
Sent: 04 May 2016 09:32
To: BROECKAERT Fabrice
Cc: [redacted] ECHA Classification; [redacted] BOWMER Tim
Subject: RE: Pinoxaden: questions to Syngenta
Attachments: Syngenta response to questions from ECHA on pinoxaden .docx

Follow Up Flag: Follow up
Flag Status: Completed

Dear Fabrice, herewith a document addressing the question you posed on pinoxaden Best regards
[redacted]

-----Original Message-----
From: [redacted]
Sent: 27 April 2016 07:17
To: BROECKAERT Fabrice
Cc: [redacted] ECHA Classification; [redacted] BOWMER Tim
Subject: Re: Pinoxaden: questions to Syngenta

Hi Fabrice, I contact [redacted] this morning and pass on your questions.
Best regards
[redacted]

Sent from my iPad

> On 27 Apr 2016, at 07:10, BROECKAERT Fabrice <Fabrice.BROECKAERT@echa.europa.eu> wrote:
>
> Dear [redacted]
>
> We hope you are doing well.
>
> Could you please forward RAP/RAC questions below to Syngenta? The RAP/RAC questions related to the attached paper. If possible, we would like the answers by 3rd May, which is the deadline for the revised ODD/RCOM by the Rapporteurs.
>
> "We would like to ask the following specific questions on the Syngenta document "Pinoxaden reporting of adverse effects in the workforce 24.03.2016", as there are still some uncertainties which might be easy for Syngenta to clarify.
>
> 1) In this paper a total of 41 adverse reactions is listed - one injury requiring first aid treatment and 2 cases of occupational illness. We would like to know what kind of effect required first aid treatment. And second, what kind of occupational illness was seen - it is later mentioned in this document, that it was a category 2 skin occupational illness, what does that mean?
> 2) It is further mentioned on page 3 in the document that no further cases (respiratory cases?) were seen after 2009 (when a lower OEL was introduced). However, in the table above "effect by year" 13 resp. effects, one skin and one skin/eye effect are listed after 2009. We would like to have an explanation for this.
> 3) In the document it is mentioned that 8 irritation cases (5 resp., 3 skin) were seen in another production site (3rd party). Is it known how many workers have been exposed at this site in total?
> 4) In general it would be useful if an explicit description of the individual cases would be made available to us: how many, at which year, where the same individuals counted twice or even more often in subsequent years - as indicated for two cases with asthma like symptoms?
>
> Thank you very much!
>

> Kind regards
> Fabrice
> _____
> Fabrice Broeckaert, PhD, ERT
> Senior Scientific Officer - Toxicology Classification and
> Prioritisation Unit European Chemicals Agency Annankatu 18, P.O. Box
> 400, FI-00121 Helsinki, Finland
> Tel.: +358 [redacted]
> fabrice.broeckaert@echa.europa.eu
> echa.europa.eu
>
> The above represents the opinion of the author and is not an official position of the European Chemicals Agency. This email, including any files attached to it, is intended for the use of the individual to whom it is addressed. If you have received this message in error, please notify the author as soon as possible and delete the message.
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> <Pinoxaden_rep.of adverse effects in the workforce_24 03 2016_2.docx>

Syngenta response to questions from ECHA on the document "Pinoxaden reporting of adverse effects in the workforce 24.03.2016"

1) *In this paper a total of 41 adverse reactions is listed – one injury requiring first aid treatment and 2 cases of occupational illness. We would like to know what kind of effect required first aid treatment. And second, what kind of occupational illness was seen - it is later mentioned in this document, that it was a category 2 skin occupational illness, what does that mean?*

Syngenta response:

a. Effect requiring first aid:

In July 2008 unintended exposure to pinoxaden occurred during the unloading of flexible intermediate bulk containers (also known as FIBCs or big bags containing 500/600kgs material) of technical pinoxaden from a truck. The affected individual reported irritation to the eye and was referred to the medical centre. Medical treatment was given and the individual returned to work without loss of any work time.

b. Occupational illnesses:
   i. A Category 1(respiratory - see below) occupational illness was recorded in 2009 when respiratory symptoms were diagnosed by the onsite physician as occupational asthma, although not attributable to pinoxaden as no defining bronchial provocation challenge or immunological tests were performed.
   ii. A Category 2(skin) occupational illness was recorded in 2011 when an adverse skin reaction was diagnosed by a consultant dermatologist as allergic contact dermatitis which was likely attributable to pinoxaden. The individual involved had been working in the pinoxaden manufacturing plant since 2004.

The company has a number of Codes of Practice in support of the Syngenta HSE Policy, including HSE Performance Reporting. When reporting occupational illnesses, cases will include, but are not restricted to cases that are required to be reported under any national occupational illness reporting schemes such as OSHA 300 record keeping rule in the US or RIDDOR – Reporting of Injuries, Diseases and Dangerous Occurrences Regulation in the UK. In alignment with such schemes, Syngenta have agreed to use the following categories:

- Category 1 Respiratory Disease
- Category 2 Skin Disease
- Category 3 Cancer and Malignant Blood Disease
- Category 4 Other Illnesses Caused by Chemical Agents
- Category 5 Work-related Upper Limb Disorder
- Category 6 Other Musculoskeletal Disorders
- Category 7 Noise Induced Hearing Loss

- Category 8 Occupational Illness Caused by Biological Agents (Inc. Travel Illness)
- Category 9 Work-related Stress Illnesses
- Category 10 All other Occupational Illnesses
- Category 11 Adverse reactions – these cases are non-reportable under OSHA/RIDDOR

2) *It is further mentioned on page 3 in the document that no further cases (respiratory cases?) were seen after 2009 (when a lower OEL was introduced). However, in the table above "effect by year" 13 resp. effects, one skin and one skin/eye effect are listed after 2009. We would like to have an explanation for this.*

Syngenta response:

The sentence would have been better expressed as 'no new cases of Category 1 (respiratory) occupational illness'

Reported adverse reactions (Category 11) were confined to one manufacturing plant in Omaha. Details of the incidents are given below:

Individual	Adverse effect	Number of reports					
		2010	2011	2012	2013	2014	2015
OM1	Wheezing (first reported 2009)	3	2	1	2		
	Eye/skin irritation	1	-	-	-		
OM2	Cough/sneeze	1	-	-	-		
OM3	Wheeze was claimed but no corroboration		1				
OM8	Wheeze – pre-existing asthma effect likely attributable to pivalic acid. Washing forklift – no confirmed exposure to pinoxaden		1				
OM9	Skin irritation – no exposure to pinoxaden	1					
OM11	Cough – no confirmed exposure to pinoxaden				1		
OM12	Wheeze – this person has made several reports of being susceptible to organic vapour and has undergone extensive medical review. The 2013 report did not confirm any PXD exposure, and lung function had not been compromised when tested.				1		
	Totals	**6**	**4**	**1**	**4**	**0**	**0**

The majority of reports were from one individual who was particularly sensitive to pinoxaden and who was first exposed prior to the introduction of more stringent control measures. For all other cases, reports were of a single incident and there was little/no evidence of

association of reported incidents with exposure to pinoxaden. There have been no reports of adverse health incidents in the manufacturing or 3 formulation plants since 2013 and no reported adverse effects associated with mixing/loading/spraying pinoxaden containing products.

3) *In the document it is mentioned that 8 irritation cases (5 resp., 3 skin) were seen in another production site (3rd party). Is it known how many workers have been exposed at this site in total?*

Syngenta response:

The third party formulation site was based in Canada and employed a total of 50 people, of which 10 worked with pinoxaden technical material.

In the first report, dated Jan 2006, 5 people were exposed to dust from a large bag of pinoxaden which was being moved on a forklift truck and was 'heavily placed' on the floor. All reported coughing.

In the second incident in November 2008, 3 people were shoveling approximately 30 kg of technical pinoxaden into a hopper from a partially emptied big bag. They were wearing PPE which was deemed appropriate at the time. All 3 reported skin irritation.

4) *In general it would be useful if an explicit description of the individual cases would be made available to us: how many, at which year, where the same individuals counted twice or even more often in subsequent years - as indicated for two cases with asthma like symptoms?*

Syngenta response:

Details of individual adverse health reports from 2010-2013 are given below:

OM1	Respiratory	07/02/2013	Cough, sneeze, wheeze.	Working in office and visited unit not handling PXD. After 1 hour, noticed some congestion but didn't use inhaler. Coughing and sneezing continued throughout day but resolved by evening. No issues next day.
OM1	Respiratory	04/02/2013	Cough, short breath	Working in office when colleague from formulation unit came in for 5 minutes. Solvent smell and possible contamination on uniform or the hooded winter coat.

OM1	Respiratory	28/02/2012	Cough, short breath, itchiness	Walked past area where colleagues were breaking down boxes that had been around PXD big bags
OM1	Respiratory	25/04/2011	Shortness of breath, wheeze, cough	Speaking with colleagues from formulation unit, who were still wearing plant uniform
OM1	Respiratory	08/03/2011	Shortness of breath, wheeze. Used inhaler	Went to pinoxaden formulation unit despite being advised to stay away.
OM1	Respiratory	19/05/2010	Shortness of breath, used inhaler.	Stood next to worker from formulation unit who were wearing their plant uniform that may have been contaminated.
OM1	Respiratory	25/03/2010	Sneezing, shortness of breath	Working with bag baler equipment. No visible contamination.
OM1	Skin Eyes Respiratory	03/03/2010	Swelling around eyes, shortness of breath	Walked by formulation unit where 2 big bags of pinoxaden had recently been taken by on fork lift truck.
OM1	Respiratory	01/02/2010	Sneezing, puffy eyes, coughing, wheeze	Working in office but symptoms developed when colleagues from production area visited still wearing plant clothing.
OM2	Respiratory	01/02/2010	Sneezing/coughing	Colleague to OM1 who reported similar symptoms when office was visited by workers from production area.
OM3	Respiratory	23/07/2011	Shortness of breath, wheeze. No witness to confirm symptoms	Maintenance Employee experienced respiratory symptoms when working around minibulk filler while pinoxaden formulation was being packaged. Employee has had issues with dry pinoxaden tech but no reported issues around finished formulated product.

OM8	Respiratory	30/08/2011	Shortness of breath, wheeze. No witness to confirm symptoms	Washing down muddy forklift in open wash bay. Only realized that other equipment in the bay was from the PXD formulation plant when colleagues returned wearing respirators and protective suits. Assumed that he had been exposed to PXD or pivalic acid resulting from breakdown of PXD in presence of water but no supporting evidence of exposure or the presence of symptoms alleged. Has pre-existing asthma.
OM9	Skin	11/02/2010	Skin red and itchy on wrists.	Employee handled paperwork from the production area; She had no previous exposure to or reaction from pinoxaden.
OM11	Respiratory	13/02/2013	Cough	Driving Fork Lift Truck - no known exposure.
OM12	Respiratory, eyes	13/02/2013	Shortness of breath, red eyes	Noticed some containers of PXD in roped off area in open air. Wind blowing in direction of employee, who walked away from containers. Felt some discomfort and breathing difficulties. Went to clinic for tests - eyes red, no wheeze, spirometry same as that taken Sept 2012. PXD containers swabbed, no evidence of PXD on surface.

J Botham/K Ledgerwood April 29 2016