

Message

From: ROOSE, BART [AG/5035] [/O=MONSANTO/OU=EA-5035-01/CN=RECIPIENTS/CN=93643]
Sent: 2/13/2016 6:06:31 PM
To: KLOPF, GARY J [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=162545]; GARNETT, RICHARD P [AG/5040] [/O=MONSANTO/OU=EA-5041-01/cn=Recipients/cn=107838]
CC: FLAGG, LISA M [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=551087]; LEI, PENG [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=812920]; MANNION, RHONDA M [AG/1000] [/O=MONSANTO/OU=NA-1000-01/cn=Recipients/cn=226139]; VERWAEST, KIM [AG/5035] [/O=MONSANTO/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=KVERW]
Subject: RE: PPCR: EMEA, 20160208, MON 76952 (SuperZanussi), NNG and formaldehyde testing before and after aging

All,

I talked to Kim to understand current practice:

We do real ageing (under GLP) at Gembloux, but they cannot measure NNG under GLP

This aged sample is then send to STL for GLP NNG data (we know initial NNG results from Antwerp lab, but that is not GLP)

If we cannot wait for real aged data, and we need accelerated ageing data

My comment is to be prudent and take into account the chemistry of the formulation ingredients.

p.e.: The Zanussi amineoxide ingredient can be more sensitive to heat, so prudence is needed

I would suggest we agree in writing that 'bad results' of NNG due to accelerated ageing can be caused by the heat level and is therefore not representative for 'normal ageing'.

We need to get a chance for a reanalysis at lower temperature, in other words the result is not final, not binding

If we cannot do this as a general statement, we need to rely on chemistry evaluation to assess the risk upfront

Regards, Bart

From: KLOPF, GARY J [AG/1000]
Sent: vrijdag 12 februari 2016 19:19
To: GARNETT, RICHARD P [AG/5040]; ROOSE, BART [AG/5035]

Cc: FLAGG, LISA M [AG/1000]; LEI, PENG [AG/1000]; MANNION, RHONDA M [AG/1000]

Subject: RE: PPCR: EMEA, 20160208, MON 76952 (SuperZanussi), NNG and formaldehyde testing before and after aging

Richard, Bart --

I agree with your comments on temperature selection. If I'm remembering correctly, doesn't this harken back to what was done with the current Zanussi formulation (MON 79351)? If so, can the same protocol be followed for any work done in this case (and then utilize whatever justification was developed then)?

Gary (314-694-8784)

From: GARNETT, RICHARD P [AG/5040]

Sent: Wednesday, February 10, 2016 5:55 AM

To: FLAGG, LISA M [AG/1000]; ROOSE, BART [AG/5035]; KLOPF, GARY J [AG/1000]; LEI, PENG [AG/1000]

Subject: RE: PPCR: EMEA, 20160208, MON 76952 (SuperZanussi), NNG and formaldehyde testing before and after aging

Bart and all,

This is not a unique request. Recall that we undertook storage stability on representative liquid and dry products to address similar questions from a small number of member states during the registration and re-registration processes post Annex I inclusion. This was derived from the old FAO spec (2001/2)

.5.2 Stability at elevated temperature (MT 46.3)

After storage at 54 + 2°C for 14 days, the average determined Glyphosate content must not be lower than 95 % relative to the determined content found before storage and the product shall continue to comply with .3.3.1, 3.3.2 and .4.1.

where .3.3.1 and .3.3.2 are formaldehyde and NNG respectively. [the new FAO spec does not reference impurities after storage but as you know there are so many mistakes currently being corrected that, perhaps, countries tend to ignore it?]

As far as I can see, the EU legislation has never specified a requirement for measuring impurities after storage but it is a logical request, particularly given the FAO spec.

So, I think we need to address the point but don't want to do this for all formulations in the re-registration. It may be possible to argue that the study on MON 78294 is adequate to address other soluble concentrates. If a new study is needed, then I agree with Bart's proposal on using the lowest allowable temperature (30C for 18 weeks or 35 for 12 weeks if time is critical).

I will not be in Brussels office until 22 Feb, so will engage Wibke by phone and email if we can agree a recommendation to her and the analytics team. Lisa, can you bring up with Brianna before "the horse has bolted" please.

regards

Richard

From: FLAGG, LISA M [AG/1000]

Sent: Tuesday, February 09, 2016 23:05

To: ROOSE, BART [AG/5035]; GARNETT, RICHARD P [AG/5040]; KLOPF, GARY J [AG/1000]; LEI, PENG [AG/1000]

Subject: RE: PPCR: EMEA, 20160208, MON 76952 (SuperZanussi), NNG and formaldehyde testing before and after aging

I'm looping in Gary and Peng – are there other considerations to take into account with this request (see email string re: SuperZanussi in EU)

Lisa Flagg

Global Product Quality Lead, Crop Protection

Office: 314-694-1717

Mobile: 314-856-3810

From: ROOSE, BART [AG/5035]

Sent: Monday, February 08, 2016 11:04 AM

To: GARNETT, RICHARD P [AG/5040]; FLAGG, LISA M [AG/1000]

Subject: RE: PPCR: EMEA, 20160208, MON 76952 (SuperZanussi), NNG and formaldehyde testing before and after aging

Richard, thanks for forward

The first time I see this

- Request for method validation for NNG and FORMALDEHYDE
- Relevant impurities after ageing ?????
 - o is this in FAO manual? I cannot remember having seen this
 - o **I ask for caution for NNG:** the higher the temperature, the more chance you have minor decomposition (ppb level) maybe creating NNG
 - o To avoid false elevated levels, ageing effect on NNG should be done at the lowest possible temp (not 2 weeks 54°C, more weeks at lower temp)
 - o **I would push back on this test because NNG formation during ageing should not be done with forced (accelerated) ageing**

Regards, Bart

From: GARNETT, RICHARD P [AG/5040]

Sent: maandag 8 februari 2016 13:38

To: FLAGG, LISA M [AG/1000]; ROOSE, BART [AG/5035]

Subject: FW: PPCR: EMEA, 20160208, MON 76952 (SuperZanussi), NNG and formaldehyde testing before and after aging

FYI

From: MEYER, WIBKE [AG/5040]

Sent: Monday, February 08, 2016 12:16

To: WHITE, BRIANNA [AG/1005]

Cc: KAEMPFE, TERRY A [AG/1000]; HAY, JANELL D [AG/1000]; BRADDOCK, PHILIP K [AG/1000]; GARNETT, RICHARD P [AG/5040]; LAMITOLA, STEPHEN [AG/1000]; GOLEY, JEAN C [AG/1005]; HOLLAND, ELAINE M [AG/1000]; GUSTIN, CHRISTOPHE [AG/5040]; MIDGLEY, BRIAN [AG/5040]; MANNION, RHONDA M [AG/1000]; VERWAEST, KIM [AG/5035]

Subject: PPCR: EMEA, 20160208, MON 76952 (SuperZanussi), NNG and formaldehyde testing before and after aging

Dear Brianna,

For the submission of MON 79652 (SuperZanussi) in the EU we have to provide data on the content of relevant impurities of the formulation, before and after storage. All studies must be GLP.

MON 76952 samples can be provided from Antwerp. I copy Kim for the arrangement of samples.

#	Item	Requestor's Input
1	Who are the teams that need to respond to this request?	Product Chemistry
2	What product(s) does this request support and for what agency, region and/or business unit	MON 76952 Submission in all member states of the EU For North: Denmark For Central: UK For South: France
3	When is the target deadline for the response and identify the implications if the deadline cannot be met	Target deadline for validate methods and accelerated aging: end August 2016 Tier 2 summaries target date: end October 2016 Implications of not meeting the deadline: Late submission, reputation damage with authorities and ultimately late launch of product
4	What is being asked for and what should the final work product be (e.g GLP study, white paper, email responses, publications)	<ul style="list-style-type: none"> • Validated method for NNG and formaldehyde in MON 76952 (GLP) • Accelerated aging study (14 d at 54 °C) + content of NNG and formaldehyde before and after aging (GLP) • storage stability study at ambient temperature in commercial packaging + content of NNG and formaldehyde before and after 1 and 2 years

		ageing (GLP)
		<ul style="list-style-type: none"> • Tier 2 summaries for inclusion in the dossier
5	<i>Please note if additional outside spend may be needed - comment on the progress towards budget approval and addition to forecast</i>	

If you have questions please let me know.

Thanks.

Kind regards,

Wibke

Dr. Wibke Meyer

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