

From: "CTGB Servicedesk"
Sent: Fri, 10 Jan 2025 15:22:57 +0100
To: ""5.1.2.e"" <5.1.2.e@raatgroesbeek.onmicrosoft.com>
Cc: "CTGB Servicedesk" <servicedesk@ctgb.nl>
Subject: 24001945 - RAAT Agrochemical Trading - K-PAK scope 1107/2009
Categories: 5.1.2.e

Geachte 5.1.2.e

Wij zijn op de hoogte van de wijzigingen in het scope-document met betrekking tot het Siltac en de inclusie van K-PAK als gewasbeschermingsmiddel. Het is ons beleid om de richtlijnen in dit document te volgen, wat zou betekenen dat producten zoals Siltac en K-PAK onderhevig zijn aan wettelijke regelgeving en een toelating vereisen. Nederland is van mening dat deze producten inderdaad een gewasbeschermingsmiddel zijn, gezien het feit dat ze op planten worden gespoten om insecten te doden. Bovendien is er een duidelijke aanbeveling van het RIVM 'dat dit soort plaagbestrijdingsmiddelen worden opgenomen in de definitie van werkzame stoffen in de EU-regelgeving voor biociden en voor plantbeschermingsmiddelen'. We merken op dat er op dit moment nog een lopende discussie is binnen SCoPAFF, die ook een discussie omvat over de uitvoering van de statuswijziging in het scope-document.

Het Ctgb heeft geen handhavende bevoegdheid en houdt geen toezicht op producten die op de markt zijn. De taak van Ctgb is niet het onthouden van toestemming om producten te verkopen in Nederland die niet, of wel, onder de werkingssfeer vallen van de EU verordening 1107/2009. De taak van Ctgb is het beoordelen van toelatingsaanvragen en advisering van de Minister o.a. ten aanzien van casussen die zijn opgenomen of mogelijk zullen worden opgenomen in het scope document van de Commissie. Wij kunnen u een toelichting geven op de casus in het scope document zodra de Europese besluitvorming tot een eenduidige conclusie heeft geleid. Wij begrijpen dat er momenteel een onduidelijke situatie is ontstaan maar zo lang de Europese besluitvorming nog voort duurt kunnen wij helaas geen opheldering geven.

Wanneer het antwoord onvoldoende duidelijk is of u naar aanleiding van dit bericht verdere vragen heeft stelt u die dan gerust.

Gebruikt u a.u.b. ons [contactformulier](#) om nieuwe vragen aan de Servicedesk te stellen.

Met vriendelijke groet,

5.1.2.e

Medewerker Servicedesk / Servicedesk officer

Ctgb

College voor de toelating van gewasbeschermingsmiddelen en biociden / Board for the Authorisation of Plant Protection Products and Biocides

Bezoekadres / visiting address:

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T (31) 0317 471810

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From: 5.1.2.e <5.1.2.e@raatgroesbeek.onmicrosoft.com>
Sent: dinsdag 7 januari 2025 11:54
To: CTGB Servicedesk <servicedesk@ctgb.nl>
Subject: 24001945 - RAAT Agrochemical Trading - K-PAK scope 1107/2009

Geachte lezer,

Zoals al meermaals aangegeven ondervinden wij economische schade omdat u ons niet gelijk behandelt als concurrenten. Stix en Siltac mag wel verkocht worden en u geeft ons geen toestemming om K-Pak te verkopen.

De economische schade die ik als distributeur ondervind is nu al meer dan €100.000.

U dwingt mij, als ik niet op korte termijn (binnen 1 week) gelijk behandeld wordt, deze kwestie bij de ACM aan de orde te stellen.

Ik hoor graag spoedig van u.

Met vriendelijke groet,

5.1.2.e

RAAT Agrochemical Trading
Generaal Gavinstraat 232
6562 MP Groesbeek
The Netherlands
Tel 5.1.2.e
Mob 5.1.2.e

Van: 5.1.2.e

Verzonden: woensdag 11 december 2024 10:30

Aan: CTGB Servicedesk <servicedesk@ctgb.nl>

Onderwerp: FW: K-Pak.

Geachte lezer,

De concurrentie (Siltac en Styx) is nog steeds bevoegd om in Nederland te verkopen.

K-Pak wordt door de Standing Committee, wiens oordeel u zegt te volgen, als een soortgelijk product gezien.

Wij ondervinden grote financiële schade omdat u ons niet in staat stelt om K-Pak te verkopen.

Nogmaals aan u de vraag om ons gelijk te behandelen en dus ook toestemming te geven om K-Pak te verkopen.

Met vriendelijke groet,

5.1.2.e

RAAT Agrochemical Trading
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Mob 5.1.2.e

Van: 5.1.2.e

Verzonden: vrijdag 6 december 2024 10:26

Aan: CTGB Servicedesk <servicedesk@ctgb.nl>

Onderwerp: FW: K-Pak.

Geachte lezer,

In navolging van mijn mails van 19 en 25 november stuur ik u onderstaand het antwoord dat ik van de Belgische overheid krijg. In België mag ik K-Pak gewoon verkopen, wetende dat binnen de Standing Committee discussies plaatsvinden over K-Pak en soortgelijke producten.

Ik zou ook graag van u de toestemming ontvangen dat ik K-Pak in Nederland mag verkopen.

Met vriendelijke groet,

5.1.2.e

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The Netherlands

Tel 5.1.2.e

Mob 5.1.2.e

Van: 5.1.2.e (FOD VVWL - SPF SPSCAE) 5.1.2.e <5.1.2.e@health.fgov.be>

Verzonden: donderdag 5 december 2024 17:05

Aan: 5.1.2.e <5.1.2.e@maatgroesbeek.onmicrosoft.com>

Onderwerp: RE: K-Pak.

Dear 5.1.2.e

You contacted us in the past regarding this product, and at that time we already confirmed that you could market this product. See that conversation in attachment.

As it stands you can still sell this product on the Belgian market. As you know however, this product and others like it are the subject of a serious discussion regarding how to handle these. The situation towards the future is unpredictable, and depending on the outcome of this European discussion, we might have to end marketing of this product without an approval on short notice. We are in favour of a harmonised solution in the EU

With kind regards



Volksgezondheid
Veiligheid van de Voedselketen
Leefmilieu

5.1.2.e

Titre Fonction

5.1.2.e <5.1.2.e@health.fgov.be>

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Galileelaan, 5/2 • 1210 Brussel • www.health.belgium.be



Van: 5.1.2.e <5.1.2.e@raatgroesbeek.onmicrosoft.com>

Verzonden: maandag, 2 december 2024 11:21

Aan: 5.1.2.e (FOD VVVL - SPF SPSCAE) <5.1.2.e@health.fgov.be>

Onderwerp: RE: K-Pak.

You don't often get email from 5.1.2.e@raatgroesbeek.onmicrosoft.com. [Learn why this is important](#)

Dear 5.1.2.e

Thanks.

I'm looking forward to receive your answer.

Kind regards,

5.1.2.e

Van: 5.1.2.e (FOD VVVL - SPF SPSCAE) 5.1.2.e@health.fgov.be>

Verzonden: maandag 2 december 2024 11:19

Aan: 5.1.2.e <5.1.2.e@raatgroesbeek.onmicrosoft.com>

Onderwerp: RE: K-Pak.

Dear 5.1.2.e

My apologies, I had misread your email, and had not noticed that you mainly wanted a proof of receipt. I have heard your voicemail, I am in meetings currently so was not able to pick up.

I have received this mail, and we are internally looking at this. I hope to be able to reply to your email soon.

With kind regards

Van: 5.1.2.e <5.1.2.e@raatgroesbeek.onmicrosoft.com>

Verzonden: woensdag, 27 november 2024 10:06

Aan: 5.1.2.e (FOD VVVL - SPF SPSCAE) <5.1.2.e@health.fgov.be>

Onderwerp: FW: K-Pak.

You don't often get email from 5.1.2.e@raatgroesbeek.onmicrosoft.com. [Learn why this is important](#)

Dear 5.1.2.e

I did not receive a mail back from you as proof you received my mail.

For us it is of great importance to get an answer ASAP, since we lose money every day, not being able to sell K-Pak where the competition is able to do so.

So please tell me when you will be able to answer?

Kind regards,

5.1.2.e

RAAT Agrochemical Trading

Generaal Gavinstraat 232

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Van: 5.1.2.e

Verzonden: dinsdag 19 november 2024 11:07

Aan: 5.1.2.e @health.fgov.be

Onderwerp: FW: K-Pak.

Dear Mr. 5.1.2.e

I'm 5.1.2.e distributor of K-Pak outside Poland.

Since March 2023, K-Pak, STYX and Siltac are discussed within the Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals – Legislation. The outcome of these discussions was until now that the three products involved, are considered in the scope, which means they should be seen as PPP that have to be registered according to Regulation (EC) No. 1107/2009. In the list it says with K-Pak: The product contains modified trisiloxane that increase the wettability of hydrophobic surfaces including the pests (aphids and spider mites) feeding on plants, which “die as a result of disruption of physiological processes”. The latter mode of action is normally interpreted as invasive and was considered (see entry 40,100, 178, 222) as PPP.

Although the Scope and Borderline Issues list is not legally binding, Synthos Agro, (the Polish producer of K-Pak) asked the different member states if we were still allowed to sell K-Pak.

All member states asked, replied they followed the advice in the list, which means K-PAK could no longer be sold.

With this mail I like bring forward two issues:

1. K-Pak is not invasive and therefore should not been seen as a PPP.
2. The allowance to sell K-Pak.

1. **K-Pak is not invasive and therefore should not been seen as a PPP.**

The main ingredient of the K-PAK preparation is modified trisiloxane. Next to that K-Pak does not contain any chemical active substances. The committee interpretates K-Pak as invasive.

What is the definition of invasive in relation to small insects?

In relation to small insects, the term invasive generally refers to any action or process that physically, chemically, or biologically interferes with the insect's normal physiological functions, leading to harm, death, or disruption of essential systems like respiration, digestion, or reproduction. Here's how "invasive" can be defined in different contexts:

1. Physical Invasiveness:

- Definition: A product or action is considered physically invasive if it penetrates or alters the insect's external structure or body, causing injury or fatality. This could include puncturing, suffocating, or otherwise compromising the insect's exoskeleton or respiratory system (such as blocking spiracles).

2. Chemical Invasiveness:

- Definition: A product is chemically invasive if it enters the insect's body and disrupts internal systems, often through ingestion or absorption. These chemicals typically affect nerve, hormonal, or digestive systems.

3. Biological Invasiveness:

- Definition: Biological invasiveness refers to methods that introduce biological agents (such as pathogens, predators, or parasitic organisms) to harm or kill insects by infecting or preying on them.

Non-Invasive in Relation to Small Insects:

A non-invasive product or action does not interfere with the internal physiology of the insect. Instead, it works by:

- Physically immobilizing (e.g., sticky traps, silicone barriers).
- Creating physical barriers that deter pests from landing or feeding on plants (e.g., reflective mulch, silicone films).
- Deterring behaviorally (e.g., repelling insects without causing harm).

Trisiloxanes are primarily known as super-spreaders or wetting agents, often used in agricultural applications to improve the efficacy of pesticides, fertilizers, and other treatments by enhancing the coverage and penetration of these substances on plant

surfaces. However, on their own, trisiloxanes are not typically considered invasive to small insects like aphids or spider mites because they don't directly interfere with the insects' internal biological processes.

Trisiloxanes reduce the surface tension of liquids, allowing better spreading on plant surfaces. This means they enhance the spread of pesticides, but do not themselves act as a pesticide or chemically disrupt the insect's physiology.

Non-Invasive Effect: Since trisiloxanes don't enter the insect's body or disrupt their biological systems (such as the nervous system), they are not considered chemically invasive.

Trisiloxanes on their own do not have direct insecticidal properties, meaning they do not kill insects by poisoning them or interfering with their physiological processes.

Environmental Impact: Trisiloxanes are generally considered safe for humans, animals, and the environment in the concentrations typically used in agricultural applications. This is because they do not accumulate in biological systems or cause harm to non-target organisms.

Trisiloxanes are valued for their ability to reduce environmental impact by enhancing the efficiency of treatments, meaning less chemical use may be required overall.

Sources:

Next to general knowledge about how trisiloxanes are used in agricultural and chemical applications following articles:

1. **"The Onset and Early Stages of Dynamic Wetting of Superspreading and Non-Superspreading Trisiloxane Surfactant Solutions on Hydrophobic Surfaces":**
 - This study focuses on the wetting behavior of trisiloxanes like **S240** (a superspreader) and compares it to non-superspreaders. It confirms the physical mode of action in spreading on hydrophobic surfaces, which is relevant for their role in agriculture as non-invasive surfactants([MDPI](#), Published Jan. 2024).
2. **"Surface Tension Behavior of Superspreading and Non-Superspreading Trisiloxane Surfactants":**
 - This article explains how trisiloxane surfactants work by reducing surface tension, thereby promoting spreading. It highlights that their mechanism is **physical**, focusing on surface interactions, and does not invade the biological systems of pests ([SpringerLink](#), Published April 2023).
3. **"Research Progress in Structure Synthesis, Properties, and Applications of Small-Molecule Silicone Surfactants":**
 - This paper explores the synthesis and properties of trisiloxane surfactants, with a focus on their application in various industries, including agriculture. The article emphasizes their role as surfactants rather than active pest control agents, further supporting their non-invasive nature([SpringerLink](#), Published April 2024).

These articles collectively support the idea that **trisiloxanes** act as physical surfactants, enhancing the performance of agrochemicals without directly affecting pests on a biological level. You can find more details in these studies on [SpringerLink](#) by searching for the titles.

Also, the polymers in K-PAK are on the ORGANIC MATERIALS REVIEW INSTITUTE (OMRI) list in the United States of America. Therefore, they can be used in certified organic production in accordance with the provisions of the USDA National Organic Program. K-PAK ingredients are listed in the following chemical inventories: European Inventory of Existing Chemical Substances (EINECS), TSCA Chemical Substance Inventory US EPA, Japanese Existing and New Chemical Substances (ENCS), Australian Inventory of Chemical Substances (AICS), ECL, PICCS CHINA, Canada Non-Domestic Substance List (NDSL). For all monomers of silicone copolymers contained in the preparation, the registration conditions required by Regulation EC No. 1907/2006 of the European Parliament and the European Council have been met.

Thus, our conclusion is: K-Pak is not invasive and should not be seen as a PPP.

2. The possibility to sell K-Pak.

As I told you in the first lines of this mail member states told Synthos Agro we were not allowed to sell K-Pak. However, we learned Siltac and STYX are still sold in the different member states, including yours. It seems that they are allowed to do so, as long as the discussion about these products is going on in the committee, or the committee was convinced by similar information as above about the non-invasiveness of trisiloxanes, showing these products do not disrupt the physiological processes of the insects.

Here also we ask you for alignment of conclusions and ask you to allow us to sell K-Pak as from today.

Next to giving us allowance to sell K-Pak in your country I like to ask you to bring forward the information about K-Pak not being invasive described above in the Standing Committee.

I'm looking forward to receive your comments as soon as possible giving us the same change as our competition.

Kind regards,

5.1.2.e

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