



HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 BESLUIT AMBTSHALVE WIJZIGING

HET COLLEGE BESLUIT tot wijziging van de toelating van

DEGESCH-PLATES, DEGESCH-STRIP

De thans geldende gebruiksvoorschriften, zoals opgenomen in de samenvatting van de productkenmerken (SPC), worden met ingang van [datum: PM] gewijzigd.

1.1 Wettelijke grondslag

De rechtsgrond van de wijziging is gebaseerd op art 48 (a) van Verordening (EU) 528/2012. Voor de gronden van dit besluit wordt verwezen naar bijlage I bij dit besluit.

1.2 Aflever- en opgebruiktermijnen

Aan de beperking van het gebruiksvoorschrift liggen onacceptabele veiligheids- en gezondheidsrisico's voor de mens ten grondslag. Daarom zijn respijttermijnen voor afleveren en opgebruik als bedoeld in artikel 52 Verordening (EU) 528/2012 van toepassing voor verpakkingen met de oude etikettering. Vanwege deze risico's zijn maximale respijttermijnen niet mogelijk. Er is wel ruimte voor beperkte respijttermijnen. Daarom worden een aflevertermijn van 6 maanden en aansluitend een beperkte opgebruiktermijn van 3 maanden vastgesteld. Hiermee is afleveren en opgebruik van verpakkingen met de oude etikettering mogelijk om voorraden in de keten af te kunnen bouwen.

1.3 Samenvatting van Productkenmerken (SPC)

De productkenmerken waaronder de gebruiksvoorschriften worden gewijzigd als voorzien in de SPC, bijgevoegd bij dit besluit. Het onder gas transporteren van voorraden en goederen is niet toegestaan. Tevens worden restrictiezinnen toegevoegd en aangescherpt.

De SPC wordt [PM date] van kracht en wordt gepubliceerd in de Ctgb toelatingendatabank en de Europese toelatingendatabank van ECHA. Het middel mag slechts worden gebruikt voor de in het SPC weergegeven toepassingen met inachtneming van de daarin weergegeven gebruiksvoorschriften.

Beroepsmogelijkheid

Een ieder wiens belang rechtstreeks bij dit besluit is betrokken, kan op grond van artikel 4 van Bijlage 2 bij de Awb, tegen dit besluit binnen 6 weken na bekendmaking van het besluit beroep instellen bij het College van Beroep voor het bedrijfsleven, Postbus 20021, 2500 EA 's-Gravenhage. Het beroepschrift moet op grond van artikel 6:5 Awb zijn ondertekend en bevat tenminste de naam en het adres van de indiener, de dagtekening, de omschrijving van het besluit waartegen het beroep is gericht, de gronden waarop het beroepschrift rust en zo mogelijk een afschrift van het besluit. Van de indiener van het beroepschrift wordt griffierecht geheven door de griffier van het College van Beroep voor het bedrijfsleven (hierna te noemen: het CBb). Nadere informatie over de hoogte van het griffierecht en de wijze van betalen wordt door de Griffie van het CBb verstrekt.

Ede, [datum: PM]

Het college voor de toelating van
gewasbeschermingsmiddelen en biociden,
voor deze:
de voorzitter,

Drs. R.J.T. van Lint

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I: Onderbouwing bij het besluit

Phosphine gas is used to protect stored goods by controlling insects during transport and storage. It is the most toxic gas that is used for fumigation. The gas is odorless and colorless and can be fatal in relatively low concentrations.

In case plants or (simple processed) plant products are fumigated, this should be done using a plant protection product. If the goods consist of non-plant material or processed plant material a biocidal product is applied. This distinction is made because of the use areas as defined in the Plant Protection Product Regulation (1107/2009/EC) and the Biocidal Product Regulation (528/2012/EC). The composition of plant protection products and biocidal products authorized for fumigation can be identical.

Authorized products generating phosphine gas consist of tablets containing aluminum phosphide or magnesium phosphide which are placed in the storage space or cargo hold followed by airtight sealing of the treated space. In contact with air and moisture phosphine gas is released from the tablets which diffuses through the space and kills insects and any other animals that are present. Treatment typically lasts 3 to 8 days. After treatment the treated space is ventilated to allow the phosphine concentration to decrease to unarmful concentrations. After clearance the space can be accessed again by personnel.

In recent years several incidents with phosphine intoxications have occurred in The Netherlands. Between 2013 and 2021 the Dutch Poison Centre (NVIC) reported 14 cases of incidents with phosphine gas where people were exposed to phosphine gas.

In one case animal feed imported from abroad was transferred to an inland vessel in the port of Amsterdam. After transfer the feed cargo was declared free of phosphine, but later higher phosphine levels were measured after hospitalization of the ship's crew (all of whom recovered). This proves that phosphide tablets can be reactivated, for example after transfer, and thus present an unacceptable risk.

In a second case three inland vessels were loaded with grain from a train originating from Poland. The grain was treated with phosphide tablets, presumably in Poland during loading of the train. After transfer to the inland vessels a phosphine alarm was triggered, and a follow-up investigation demonstrated phosphine gas was present in the cargo holds of all three inland vessels.

In both cases the application of phosphide tablets was done outside The Netherlands. Upon discussing the incidents in European meetings for biocides (CA-meeting) and plant protection products (SCoPAFF), it was clear that in other member states also incidents of phosphine poisoning occurred in recent years.

The Ctgb (Dutch competent authority for Plant Protection Products and Biocides) made an analysis of the instructions for use of the authorized phosphide-based plant protection products (4) and biocidal products (1) authorized for fumigation in The Netherlands. The composition of all 5 products is nearly identical. These are some of the findings:

- a) Instructions for fumigation and degassing differ between products and differ between plant protection products and biocidal products;
- b) Not all instructions specify whether gassed loads may be transported or not;
- c) Avoiding phosphine poisoning during or after transport is possible with the addition of some restrictions to the instructions for use.

The conclusions are:

- The distinction between plant protection products and biocidal products is not relevant when looking at the level of practical application of the products by users and only add to confusion. Therefore, differences in the instructions for a safe use for plant protection products and biocides should be avoided.
- Instructions should be very clear about the way to avoid phosphine poisonings.
- Instructions should as far as safety measures is concerned, be harmonized in all EU Member States.
- Workers who take care of degassing must be able to read and know the instructions given on the label of the phosphide products that are used. In case of transport abroad, this is not the case.

The Ctgb initiative to amend the instructions for use of phosphide products is part of the national program to avoid incidents with fumigated cargo in the future. This program is described in the "[Ketenanalyse gegaste ladingen](#)" (Chain Analysis fumigated cargo), drafted by the Ministries of Infrastructure and Watermanagement, Social affairs and Employment and Agriculture, Nature and Food Quality, inspectorates and Ctgb and presented to the Dutch Parliament in April 2022.

The conclusions of the chain analysis are that regulations for transport (ADR, ADN, RID) are not robust enough for transferring all necessary information about cargo that is or has been fumigated, to the people who will handle the cargo after transport; that necessary protocols for transfer and transshipment of fumigated cargo are missing and that a coordinated enforcement strategy is lacking. It will take years to organize a harmonized robust approach for securing international transport of fumigated cargo.

It has been shown in practice that in cargo that was declared phosphine free after measuring by qualified people, phosphine gas started developing again after transshipment¹. This caused at least in one case in the Netherlands serious injury to a skipper and members of his family. In another case the gas was detected in time to prevent accidents.

Another reason to amend the current instructions for use of phosphides is that the instructions about degassing cannot be complied with and enforced in case of fumigation during transport. The degassing after transport happens in many cases far away from the site of applying the tablets and often in another country. The instructions for degassing after transport cannot be complied with because they are not available at the place of degassing. And because in most cases the degassing takes place after international transport, these instructions are not legally applicable in the country of destination. Because these instructions cannot be complied with and enforced in case of transport, the current instructions are not legally applicable and need to be amended. This can be solved by prohibiting fumigation of plant products and goods during transport.

Considerations in summary:

- Phosphine gas is highly toxic;
- There is international transport of cargo fumigated with phosphine gas within de EU;
- Accidents and nearly accidents with barges carrying a cargo fumigated with phosphine gas during transport occur;
- It is shown in practice that phosphide pills in cargo can start developing again phosphine gas after transshipment, even when the cargo is declared gas free by professional qualified personnel;

¹ See: Conclusion no 3 of the Dutch report on the incident that took place in 2019: https://www.portofamsterdam.com/sites/default/files/2020-06/onderzoekcommissie_-_fosfine_incident_met_mvs_fox_definitief.pdf

- Instructions for use need to be clear, feasible, enforceable and effective in mitigating the risks they are considered to address. The current instructions for use of phosphides, used for the fumigation of stored plants, plant products and goods, are for degassing not legally applicable because in case of transport they cannot be complied with and enforced.

The above provides indication that the authorised products no longer satisfy the requirements for authorisation as laid down in article 29 of Regulation (EC) No 1107/2009 and, respectively, article 19 of Regulation (EU) No 528/2012, specifically that they shall have no harmful or unacceptable effect to human health.

Based on these considerations and pursuant to article 44 of Regulation (EC) No 1107/2009 and article 48 of Regulation (EU) No 528/2012 the Board for Authorization of Plant Protection Products and Biocidal Products in the Netherlands (Ctgb) intends to amend the authorisation of all plant protection products and biocidal products based on aluminum phosphide and magnesium phosphide used for the fumigation of stored plants, plant products or goods. The amendment consists of an amendment of the use instructions in order to ensure a safe use.

The goal of these changes is to avoid future accidents with phosphine gas that is used for the fumigation of stored plants, plant products or goods and to make the instructions enforceable and make sure that workers can comply with the instructions.

Article 44 of Regulation (EC) No 1107/2009 and article 48 of Regulation (EU) No 528/2012 state that these articles can be used in case a product is used as authorised but the requirements for authorisation (article 19 BPR, article 29 PPPR) are not satisfied.

The incident of 2019 was evaluated by an independent inquiry committee. The committee concluded that the handling of the fumigated cargo, the required measurements and the gas-free statement were done correctly and according to the requirements. There is no indication that the phosphide product that was applied was used incorrectly, or the degassing procedure was not done up to standards². Therefore, Ctgb concludes that the phosphide product was used in compliance with the authorised use.

The incident shows that reactivation of residues of phosphide pills is possible. In the process of authorizing products based on phosphides it is assumed that reactivation is not possible. This assumption is not correct leading to incidents that can be fatal for transporters. It is the responsibility of Ctgb to use article 44 PPPR and article 48 BPR to amend the authorisations of products based on phosphide to prevent similar accidents in the future.

The restrictions are for all inland transport, so for transport via barges, trucks and trains. The restrictions are not applicable to cargo that is transported overseas.

Samenvatting van Productkenmerken (SPC)

De volgende aanpassingen worden doorgevoerd in weergegeven toepassingen en haar gebruiksvorschriften in de Summary of Product Characteristics (SPC):

- Het onder gas transporteren van voorraden en goederen via binnenvaart, over het spoor of over de weg is niet toegestaan.
- Dit middel mag alleen ingebracht worden in voorraden en goederen als DEGESCH platen of strips die na de gassing ook weer volledig verwijderd wordt.
- Alleen gasdicht afgesloten ruimten mogen met dit middel gegast worden. Buiten de ingestelde gevaren zone mag de gemeten concentratie tijdens de behandelingsperiode niet hoger dan 0.03 ppm zijn.

² See: Conclusion no 4 of the Dutch report on the incident that took place in 2019: https://www.portofamsterdam.com/sites/default/files/2020-06/onderzoekcommissie_-_fosfine_incident_met_mvs_fox_definitief.pdf

- Ruimten die gegast worden moeten voorzien zijn van een duidelijke en onuitwisbare waarschuwing die aangeeft dat er fosfinegas aanwezig is met gevaar voor de gezondheid.
- Bij gebruik van dit middel dient het gassen en ontgassen op dezelfde locatie te gebeuren.
- Het aantal DEGESCH platen of strips dat voor de gassing is toegepast moet op een waarschuwingsbord komen en de verplichting om al deze platen of strips te verwijderen voordat overslag van voorraad of goederen plaatsvindt.
- De behandelde ruimte mag pas weer betreden worden nadat de gassingsleider de ruimte gasvrij verklaard heeft.

Tevens is het gebruik van losse pillen/tabletten voor het begassen van goederen en voorraden niet toegestaan. In het geval van het middel DEGESH-PLATE, DEGESH-STRIP worden geen losse pillen/tabletten ingezet en daarom heeft dit geen gevolgen voor de toelatingen van de bestaande toepassingen.

Tevens is de omschrijving van het gebruik aangescherpt.