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| REGISTRATION REPORT  Part B  Section 0  Product Background, Regulatory Context and  GAP information |
| Product code: BAS 743 03 F  Product name(s): **DIVEXO**  Chemical active substance(s):  Ametoctradin 120 g/L  Propamocarb hydrochloride 451 g/L |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT  (authorization of product) |
| Applicant: XXXX  Submission date: October 2023 (update April 2024)  Evaluation date: May 2024  MS Finalisation date: November 2024 |

Version history

|  |  |
| --- | --- |
| When | What |
| October 2023 | Initial dRR – XXXX Doc ID 2022/2044797 |
| February 2024 | dRR update – XXXX Doc ID 2024/2000115   * Appendix 1: GAP table update |
| April 2024 | dRR update – XXXX Doc ID 2024/2010831   * Appendix 1: GAP table update |
| May 2024 | Initial RR - zRMS |
| November 2024 | Updated dRR – after MSs consultation |

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# Product background, regulatory context and GAP information

## Introduction

### Reason for application

The application was submitted for the approval of the plant protection product BAS 743 03 F, a SC formulation containing 120 g/L Ametoctradin and 451 g/L Propamocarb hydrochloride (=378 g/L Propamocarb) for the use as fungicide in Potatoes, Onion, Garlic, Tomato, Aubergine and Ornamentals.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B and Part C. The information, data and assessments provided in Registration Report, Sections B includes assessment of further data or information as required at national level in accordance with the conclusions from the EU review of the active substances. It also includes assessment of data and information relating to BAS 743 03 F where that data has not been considered in the EU review. Assessments for the safe use of BAS 743 03 F have been made using endpoints agreed in the EU review of Ametoctradin and Propamocarb (Propamocarb hydrochloride).

This application follows the data requirements for the active substances laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

### Details of zRMS(s) and concerned MS

Table ‑: Overview of zRMS and cMS

|  | zRMS, product name and authorization no. (if relevant) | (if relevant) Concerned MS, MS’ product name and authorization number (if applicable) |
| --- | --- | --- |
| Central zone | PL (DIVEXO) | AT (DIVEXO), BE (DIVEXO), CZ (DIVEXO), DE (DIVEXO), HU (DIVEXO), IE (DIVEXO), NL (SUPROVA), RO (DIVEXO), SI (DIVEXO), SK (DIVEXO) |
| Southern zone | FR (DIVEXO) |  |
| GB, XI | GB, XI (DIVEXO) |  |

### Regulatory history of the active(s)

#### Ametoctradin

Table ‑: Summary of regulatory history of CAS No: 865318-97-4

| Status |  |
| --- | --- |
| Approved in EU | Y |
| Original Inclusion Directive  or  Commission Implementing Regulation | Commission Implementing Regulation (EU) No. 200/2013 |
| RMS | The Netherlands |
| Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied) | 01.08.2013 |
| Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal) | N/A |
| Date of final Commission (re-registration) deadline (Step 2) | N/A |
| Current expiration of approval | 31.12.2025 |
| Low risk substance or Candidate for Substitution? | No |

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

* leakage of metabolite M650F04 to groundwater under vulnerable conditions

Conditions of use shall include risk mitigation measures, where appropriate.

The SANCO report for Ametoctradin (SANCO/ 12977/2012 rev 2 – 01/02/2013) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 8 November 2012 (approved 15 October 2012).

**Table 0.1‑3: Information on minimum purity of Ametoctradin**

| EU agreed minimum purity from Inclusion Directive or Implementing regulation | (if different) Minimum purity of active substance used in the product / information on available equivalency report \*, \*\* |
| --- | --- |
| 980 g/kg |  |

\* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

\*\*. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The impurities amitrole and o-xylene are of toxicological relevance and shall not exceed 50 mg/kg and 2 g/kg respectively in the technical material.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

| Endpoint | Ametoctradin | |
| --- | --- | --- |
| EU agreed endpoint from EFSA scientific report | Endpoint used |
| Acute oral, *Colinus virginianus, Anas platyrhynchos* | LD50 > 2000 mg/kg b.w. | LD50 (extrapolated, geometric mean) = 3776 mg/kg b.w. |
| Chronic toxicity to aquatic invertebrates | NOEC 0.044 mg a.s./L | NOEC 0.018 mg a.s./L\* |

\* The mysid study (CP 10.2.2/1) provides an adverse endpoint and changes the EU agreed chronic endpoint for aquatic invertebrates (previously derived from the chronic daphnia study).

#### Propamocarb

Table ‑: Summary of regulatory history of CAS No: 24679-73-5

| Status |  |
| --- | --- |
| Approved in EU | Y |
| Original Inclusion Directive  or  Commission Implementing Regulation | Commission Directive 2007/25/EC of 23/04/2007 and Reg(EU) N° 540/2011 |
| RMS | Ireland |
| Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied) | 01.10.2007 |
| Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal) | Step 1 : 01/10/2007  Date of renewal submission: 31/01/2016 |
| Date of final Commission (re-registration) deadline (Step 2) | Step 2 : 30/09/2009 |
| Current expiration of approval | 15/06/2025 (voted in March 2023 SCOPAFF) |
| Low risk substance or Candidate for Substitution? | No |

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

* the operators and workers safety. Conditions of use should include protective measures, where appropriate;
* the transfer of soil residues for rotating and succeeding crops;
* the protection of surface and groundwater in vulnerable zones;
* the protection of birds, mammals and aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate.

The SANCO report for Propamocarb (SANCO/10057/2006 – 24/11/2006) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 12/05/2006 (EFSA Scientific Report (2006) 78, 1-72, Conclusion regarding the Peer review of the pesticide risk assessment of the active substance propamocarb)

Table 0.1‑5: Information on minimum purity of Propamocarb

| EU agreed minimum purity from Inclusion Directive or Implementing regulation | (if different) Minimum purity of active substance used in the product / information on available equivalency report \*, \*\* |
| --- | --- |
| Minimum purity expressed as TK : 69% as proposed in the EFSA Scientific report (2006) 78,1-80, confirmed by an FAO specification 399.601/TK; May 2013 |  |

\* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

\*\*. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

| Endpoint | Propamocarb | |
| --- | --- | --- |
| EU agreed endpoint from EFSA scientific report | Endpoint used\* |
| It does not apply | | |

\* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

### Regulatory history of the product

This product was not the representative formulation.

The product has not been previously evaluated according to Uniform Principles.

The product has not been previously registered in any EU Member State.

## zRMS conclusion

Identity, physical and chemical properties.

Sufficient data on identity, physical and chemical properties are available for the plant protection product BAS 743 03 F.

Based on accelerated storage study, the stability data indicate a shelf life of at least 2 years at ambient temperature. However an ambient temperature shelf life study is required to confirm the proposed shelf life of 2 years for the product BAS 743 03 F. Shelf-life study is ongoing and will be provided.

Efficacy:

Using BAS 743 03 F for all proposed uses is considered safe and effective.

Toxicology and health risk:

For the aspect human health, the intended uses are considered safe – operator has to wear protective gloves, protective clothing (coverall) when handling the concentrate; ~~in case of~~ worker reaching/ picking of potato ~~ornamentals~~ (use~~s~~ no 1 ~~6-14~~) - ~~worker~~ has to wear protective gloves in addition to standard workwear ~~for up to 5 days after application when handling the treated crops~~.

Residues:

The data available are considered sufficient for risk assessment. No exceedance of the existing EU MRLs (0.05 mg/kg for potatoes; 1.5 mg/kg for onion and garlic; and 2 mg/kg for tomatoes and aubergines) for ametoctradin is expected. No exceedance of the existing EU MRLs (0.3 mg/kg for potatoes; 2 mg/kg for onion and garlic; and 4 mg/kg for tomatoes and aubergines) for propamocarb is expected. The chronic (long-term) and acute (short-term) intakes of ametoctradin and propamocarb residues are unlikely to present a public health concern. All uses can be approved.

Fate and behaviour:

The environmental fate and behaviour of the active substances and their main metabolites were assessed in the context of the Approval. Based on data reviewed during the EU review, appropriate endpoints for PEC calculations were derived in accordance with the conclusions from the EU review and national (PL) requirements. The leaching simulation run with FOCUS PELMO, FOCUS PEARL and FOCUS MACRO resulted in PECGW values below 0.1 µg/L for ametoctradin, metabolites M650F01, M650F02 and for M650F03, M650F04 for applications to acidic soil, for all FOCUS scenarios. Under alkaline soil condition, metabolites M650F03 and M650F04 exceed the threshold of 0.1 µg/L, but below 10 µg/L for all application uses and all simulated models. However, these metabolites were subjected to a non-relevance assessment including a consumer exposure assessment according to the Guidance Document1 on the assessment of the relevance of metabolites in groundwater (see section Part B section 10). Based on this assessment metabolites M650F03 and M650F04 are considered non-relevant with regard to groundwater for the proposed uses.

All leaching simulation run with FOCUS PELMO, FOCUS PEARL resulted in PECGW values below 0.1 µg/L for propamocarb HCl for all FOCUS scenarios.

In conclusion, the results demonstrate that BAS 743 03 F can be used safely without risk of ametoctradin, its metabolites and for propamocarb HCl exceeding acceptable levels in groundwater.

Ecotoxicology:

The ecotoxicology of the active substances and their main metabolites were assessed in the context of the Approval. Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed accepted uses of BAS 743 03 F poses no unacceptable to non-target organisms, if applied according to the accepted use pattern. Particular precautions to reduce the environmental concentrations resulting from BAS 743 03 F applications are not required

It should be noted that for the GAPs minor uses according to Article 51 no PEC calculations following zonal requirements are provided in this dossier B8. Thus, the risk to aquatic and soil organisms is not covered in this report.

Uses to be considered safe on the basis of EU methodology:

|  |
| --- |
| B8-B9: Uses no. 1-5  Others: Uses no. 1-14 |

Uses to be considered non-safe on the basis of EU methodology:

|  |
| --- |
| None |

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS:

|  |
| --- |
| B8-B9: Uses no. 6-14 |

The following text is to be shortened or to be amended as necessary.

All uses/ GAPs are covered by established MRLs except for use in crop. An application for amending the MRL has been submitted by MS to EFSA EFSA Project Number (if applicable).

zRMS may insert more details of the overall summary of the assessment, focusing on the main conclusions only.

1. ALL intended uses

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | |  | | | | | |  | | | GAP rev. 2.0, date: 2023-05-15 | | | | |
| PPP (product name/code): | | | | DIVEXO / BAS 743 03 F | | | | | | Formulation type: | | | Suspension concentrate (SC) (a, b) | | | | |
| Active substance 1: | | | | Ametoctradin\* (Initium) | | | | | | Conc. of as 1: | | | 120 g/L (c) | | | | |
| Active substance 2: | | | | Propamocarb hydrochloride\*\* | | | | | | Conc. of as 2: | | | 451 g/L (equivalent to 378 g Propamocarb/L) (c) | | | | |
| Safener: | | | | None | | | | | | Conc. of safener: | | | Not relevant (c) | | | | |
| Synergist: | | | | None | | | | | | Conc. of synergist: | | | Not relvant (c) | | | | |
| Applicant: | | | | XXXX | | | | | | Professional use: | | |  | | | | |
| Zone(s): | | | | Central (d) | | | | | | Non professional use: | | |  | | | | |
| Verified by MS: | | | | yes/no | | | | | |  | | |  | | | | |
| Field of use: | | | | Fungicide | | | | | |  | | |  | | | | |
| 1 | 2 | 3 | | 4 | 5 | 6 | 7 | 8 | | 9 | 10 | | 11 | 12 | 13 | 14 | |
| **Use-No. (e)** | **Member state(s)** | **Crop and/ or situation  (crop destination / purpose of crop)** | | **F, Fn, Fpn G, Gn, Gpn or I** | **Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group) | **Application** | | | | | **Application rate** | | | | **PHI** (days) | **Remarks:**   e.g. g safener/synergist per ha  (f) | |
| Method / Kind | Timing / Growth stage of crop & season | Max. number  a) per use  b) per crop/ season | | Min. interval between applications (days) | kg or L product / ha  a) max. rate per appl.  b) max. total rate per crop/season | | g or kg as/ha  a) max. rate per appl.  b) max. total rate per crop/season | Water L/ha  min / max |
| **Zonal uses (field or outdoor uses, certain types of protected crops)** | | | | | | | | | | | | | | | | | |
| 1 | BE, IE, NL | Potato (including seed potatoes) (SOLTU) | | F | *Phytophthora infestans* (PHYTIN) | SP | BBCH 21-89 | a) 3  b) 3 | | 5 | a) 2  b) 6 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.72(\*) + 2.706(\*\*) | 100/1000 | 7 | Spray interval: 5-10 days  Water volume:  NL: 150/400 L/ha  IE: 200/400 L/ha  Applications only every 2nd year | |
| 2 | PL HU, RO, SI, SK AT, CZ, DE | Potato (including seed potatoes) (SOLTU) | | F | *Phytophthora infestans* (PHYTIN) | SP | BBCH 21-89 | a) 2  b) 2 | | 5 | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 200/400 | 7 | Spray interval: 5-10 days  Dose rate range for HU, RO, SI, SK: 1,5-2 L/ha | |
| 3 | BE, IE, NL, PL, RO | Onion  (ALLCE), Garlic (ALLSA) | | F | *Peronospora destructor*  (PERODE) | SP | BBCH 14 - 39 ~~49~~ | a) 2  b) 2 | | 5 | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 200/1000 | 7 | Spray interval: 5-10 days  Water volume:  NL, PL: 200/800 L/ha  IE. 200/700 L/ha Applications only every 2nd year | |
| 4 | AT, CZ, DE, HU, SK, SI | Onion  (ALLCE), Garlic (ALLSA) | | F | *Peronospora destructor*  (PERODE) | SP | BBCH 14 - 49 | a) 1  b) 1 | | NA | a) 2  b) 2 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.24(\*) + 0.902(\*\*) | 200/1000 | 7 |  | |
| 5 | PL,  HU, RO, SK, SI | Tomato / Aubergine  (LYPES) / (SOLME) | | F | *Phytophthora infestans* (PHYTIN) | SP | BBCH ~~21~~ 40-89 | a) 2  b) 2 | | 7 | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 150/500 | 1 | Spray interval: 7-10 days | |
| Minor uses according to Article 51 (zonal uses) \* | | | | | | | | | | | | | | | | | |
| 6 | NL | Floriculture crops DTG .2)  (unprotected culture) | | F | *Peronospora sp* (PEROSP)  *Phytophthora spp (*PHYTSP) | Foliar treatment | BBCH 12-59 (Apr-Sep) | a) 2  b) 2 | | 7 | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 500 | NA |  | |
| 7 | NL | Avenue trees | | F | *Peronospora sp* (PEROSP) | Foliar Treatment | BBCH 12-59 (Apr-Sep) | a) 2  b) 2 | | 7 | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 500 | NA |  | |
| 8 | NL | Climbing Plants | | F | *Peronospora sp* (PEROSP) | Foliar Treatment | BBCH 12-59 (Apr-Sep) | a) 2  b) 2 | | 7 | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 500 | NA | Tree nursery ornamental climbing crops (e.g. *Hedera helix,* Lonicera, Clematis. *…)* | |
| 9 | NL | Conifers (incl. Christmas trees) | | F | *Peronospora sp* (PEROSP) | Foliar Treatment | BBCH-12-59 (Apr-Sep) | a) 2  b) 2 | | 7 | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 500 | NA |  | |
| 10 | NL | Ornamental shrubs (incl. roses) | | F | *Peronospora sp* (PEROSP) | Foliar Treatment | BBCH-12-59 (Apr-Sep) | a) 2  b) 2 | | 7 | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 500 | NA |  | |
| 11 | NL | Heather | | F | *Phytophthora spp (*PHYTSP) | Foliar Treatment | BBCH-12-59 (Apr-Sep) | a) 2  b) 2 | | 7 | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 500 | NA |  | |
| 12 | NL | Forest trees and hedging plants | | F | *Peronospora sp* (PEROSP) | Foliar Treatment | BBCH-12-59 (Apr-Sep) | a) 2  b) 2 | | 7 | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 500 | NA |  | |
| 13 | NL | Fruit trees and shrubs (nursery) | | F | *Peronospora sp* (PEROSP) | Foliar Treatment | BBCH-12-59 (Apr-Sep) | a) 2  b) 2 | | 7 | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 500 | NA | Ornamental crop not for fruit production | |
| 14 | NL | Perennial crops (nursery) | | F | *Peronospora sp* (PEROSP) | Foliar Treatment | BBCH-12-59 (Apr-Sep) | a) 2  b) 2 | | 7 | a) 2  b) 4 | | a) 0.24(\*) + 0.902(\*\*)  b) 0.48(\*) + 1.804(\*\*) | 500 | NA | ~~Ornamental crop~~ Tree nursery green non-woody perennials crops not for fruit production (e.g. Papaver, Geranium, Erigeron, Coydalis, Viola, Veronica, …) | |

\* *For further details on concerned ornamental crops intended in The Netherlands and better understanding of the hierarchical classification followed in this country, please refer to the Definition List of Application Areas of Crop Protection Products (DTG list) from Ctgb which contains the standard terms for application areas of crop protection products for the Legal Instructions for Use (WG). The DTG list contains agricultural and horticultural crops, public green areas, uncultivated areas and terms for non-professional use*. *Please, refer to the following direct link:*

[Definitielijst Toepassingsgebieden Gewasbeschermingsmiddelen 2.2 | Toetsingskader gewasbeschermingsmiddel | College voor de toelating van gewasbeschermingsmiddelen en biociden (ctgb.nl)](https://eur02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ctgb.nl%2Fdocumenten%2Ftoetsingskader-gewasbeschermingsmiddelen%2F2019%2F06%2F01%2Fdefinitielijst-toepassingsgebieden-gewasbeschermingsmiddelen-dtg-2.2&data=05%7C02%7Cgemma.peidro-saperas%40basf.com%7C8e21ff0d11b14e0f993808dc5560fa95%7Cecaa386bc8df4ce0ad01740cbdb5ba55%7C0%7C0%7C638479122208585391%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=X5nJSR5EjNYklrxPd40eI0rz3EiCufCFeOyYiD9FN1g%3D&reserved=0)

|  |  |  |  |
| --- | --- | --- | --- |
| Remarks  table heading: | (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  (b) Catalogue of pesticide formulation types and international coding system CropLife  International Technical Monograph n°2, 6th Edition Revised May 2008  (c) g/kg or g/l |  | (d) Select relevant  (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use. |
|  |  |  |  |
| Remarks  columns: | 1 Numeration necessary to allow references  2 Use official codes/nomenclatures of EU Member States  3 For crops, the EU and Codex classifications (both) should be used; when relevant, the  use situation should be described (e.g. fumigation of a structure)  4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application  5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.  6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated. |  | 7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3‑8263-3152-4), including where relevant, information on season at time of application  8 The maximum number of application possible under practical conditions of use must be provided.  9 Minimum interval (in days) between applications of the same product  10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.  11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).  12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.  13 PHI - minimum pre-harvest interval  14 Remarks may include: Extent of use/economic importance/restrictions |