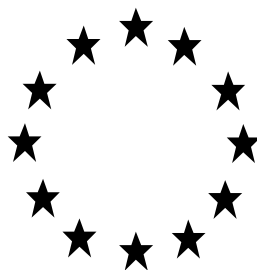


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A
BIOCIDAL PRODUCT RELATED TO MINOR
TECHNICAL MODIFICATION
AUTHORISATION**



BLACK PEARL PASTA

Product type 14

Alphachloralose

Case Number in R4BP: BC-GX024395-15

Evaluating Competent Authority: FR

Date: January 2017

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1 CONCLUSION

BLACK PEARL PASTA has been authorised in France in 2013 (FR-2013-1004 for non professional users and FR-2013-0005 for professional users) to be used against house mouse indoor by professional and non professional users.

The minor change request consists in :

- the addition of new packagings for professional and non professional uses
- the addition of three commercial names: ALPHA PASTA 4%, RACAN PASTE AF, PASTE AF

The product BLACK PEARL PASTA is compatible with the metal box, the PP bag inside a metal box and with the cartridge.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

Please refer to the product assessment report related to BLACK PEARL PASTA product authorisation (FR-2013-1004 for non professional users and FR-2013-0005 for professional users).

2.1.2 Product composition and formulation

Please refer to the product assessment report related to BLACK PEARL PASTA product authorisation (FR-2013-1004 for non professional users and FR-2013-0005 for professional users).

2.1.3 Hazard and precautionary statements¹

Please refer to the product assessment report related to BLACK PEARL PASTA product authorisation (FR-2013-1004 for non professional users and FR-2013-0005 for professional users).

2.1.4 Authorised uses

2.1.4.1 Use description²

Table 1. Use # 1 – Professional users

Product Type	PT14-Rodenticides
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	House mouse (<i>Mus musculus</i>) Adults and juveniles
Field of use	Bait stations and covered bait points could be used inside domestic, industrial and commercial buildings including farm buildings in infested areas (along walls, windows...).
Application method(s)	The product must be used by professionals specialised in rodents control only in tamper-resistant bait stations and covered bait points.
Application rate(s) and frequency	Indoor use: - Mice, high infestation: from 5g to 20g of product / bait

¹ For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

² Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence.

	<p>station or covered bait points. Distance between bait stations or covered bait points: 3 meters.</p> <p>- Mice, low infestation: from 5g to 20g of product / bait station or covered bait points. Distance between bait stations or covered bait points: 5 meters.</p> <ul style="list-style-type: none"> - The application rate or the number of sachets per bait station and covered bait points must be adapted to the effective rate. - The number of bait stations and covered bait points is function of the area of treatment and infestation rate. - Distances between bait stations or and covered bait points must be respected. - Inspect and refill the bait stations and covered bait points few days after the first application then once in a week as long as the bait is consumed. <p>Rodenticide/ acute action. The biocidal effect appears about 24 hours after ingestion of the baits.</p>
Category(ies) of users	Professionals in rodents control
Pack sizes and packaging material	<p>The product BLACK PEARL PASTA is supplied in:</p> <ul style="list-style-type: none"> - Cartridge, Plastic PP (50, 100 or 310g) - Cartridge, Metal (50g, 100g, 150g, 170g, 200g); - Individual sachet in paper (5, 10 or 20g)

2.1.4.2 Use-specific instructions for use³

- The treatment must be used alternately with other kinds of active substances in order to avoid resistances and crossresistances occurrence to anticoagulants.
- Adopt measures of integrated pest management like chemical and physical methods and hygiene practices.
- Check the efficacy of the product on site: if necessary, the reasons for reduced efficacy have to be investigated for possible evidence of resistance.
- Do not use the product in an area where resistance is suspected or established.
- The users should report straightforward to the registration holder any alarming signals which could be assumed to be resistance development.

Cartridges have to mention "Do not damage the cartridge, even when empty".
Are considered as covered bait points, bait devices providing the same level of protection for humans and the environment than bait stations, fixed so as not to be driven, avoiding direct contact the bait with the environment. These devices must be designed to keep baits inaccessible to the general public and non-target animals.

2.1.4.3 Use-specific risk mitigation measures

Do not damage the cartridge, even when empty

³ Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

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2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

<p>Are considered as covered bait points, bait devices providing the same level of protection for humans and the environment than bait stations, fixed so as not to be driven, avoiding direct contact the bait with the environment. These devices must be designed to keep baits inaccessible to the general public and non-target animals.</p>

2.1.4.7 Use description⁴

Table 2. Use # 2 – Non professional users

Product Type	PT14-Rodenticides
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	House mouse (<i>Mus musculus</i>) Adults and juveniles
Field of use	Indoor Bait stations could be used inside domestic, industrial and commercial buildings including farm buildings in infested areas (along walls, windows...).
Application method(s)	The product must be used by general public and professionals non-specialised in rodents control only in tamper-resistant bait stations.
Application rate(s) and frequency	Indoor use: - Mice, high infestation: from 5g to 20g of product / bait station or covered bait points. Distance between bait stations or covered bait points: 3 meters. - Mice, low infestation: from 5g to 20g of product / bait station or covered bait points. Distance between bait stations

⁴ Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence.

	<p>or covered bait points: 5 meters.</p> <ul style="list-style-type: none"> - The number of sachets per bait station must be adapted to the effective rate. - The number of bait stations is function of the area of treatment and infestation rate. Distances between bait stations must be respected. - Inspect and refill the bait stations few days after the first application then once in a week as long as the bait is consumed. <p>Rodenticide/ acute action. The biocidal effect appears about 24 hours after ingestion of the baits.</p>
Category(ies) of users	General public and Professionals non-specialised in rodents control
Pack sizes and packaging material	<p>The product BLACK PEARL PASTA is supplied in:</p> <ul style="list-style-type: none"> - individual sachet in paper : 5,10 or 20 g - cartridges (50 or 100g) <p>Sachets in paper are supplied in:</p> <ul style="list-style-type: none"> - prefilled bait boxes - bait boxes (100, 150, 200, 300, 400 or 500g) - doypacks (200 or 500g) - Can /Tin, Metal + PP bag (40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 360g, 400g, 440g, 480g, 520g, 560g, 1Kg, 1.5Kg) - Can /Tin, Metal (40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 360g, 400g, 440g, 480g, 520g, 560g, 1Kg, 1.5Kg) - Cardboard boxes with 2 prefilled bait boxes

2.1.4.8 Use-specific instructions for use⁵

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2.1.4.9 Use-specific risk mitigation measures

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2.1.4.10 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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⁵ Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

2.1.4.11 Where specific to the use, the instructions for safe disposal of the product and its packaging

2.1.4.12 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

2.1.5 General directions for use

2.1.5.1 Instructions for use⁶

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2.1.5.2 Risk mitigation measures

<ul style="list-style-type: none"> - Keep out of reach of children. - Keep away from food, drink and animal foodstuffs - When using do not eat, drink or smoke - Do not lay on surfaces or materials which could be in contact with food to prevent contamination of food or animal foodstuffs. - Prevent access to children, pets and wild animals. - Place the bait stations or covered bait points in sites sheltered from flooding. - Keep only in the original container. - Bait stations or covered bait points should only contain rodenticides. - Wearing gloves is recommended. - Do not open the sachet - Wash hands after use. - Remove all bait stations and covered bait points after the treatment. <p><u>To be indicated on bait stations:</u></p> <ul style="list-style-type: none"> - Do not open the bait station. - Keep out of the reach of children - Keep away from food, drink and animal foodstuffs.

2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

<p>If exposed, contact immediately a poisoning control centre or a doctor and describe the situation (give information on the label and assess the exposition rate):</p> <ul style="list-style-type: none"> - If inhaled: breathe fresh air and keep at rest. - If a contact occurs with skin: Remove contaminated clothes and wash skin with soap and rinse copiously with water. Do not use solvents or thinners. - If a contact occurs with eyes: Wash copiously under a trickle of water (tepid if possible) for several minutes, keeping eyelids open under the trickle of water. - If swallowed, seek medical advice immediately and show this container or label. Do not induce vomiting. Whatever the quantity of the product ingested, do not eat and do not drink. Install the victim in the recovery position and protect him against injury from sudden movements or convulsion. Monitor breathing. Follow the doctor's advice. In case of emergency, contact a anti poison centre. <p>Note to doctor: the product BLACK PEARL PASTA contains a depressant and convulsant of the nervous system. The bronchial congestion is fast. The treatment is symptomatic, there is no specific antidote.</p>

⁶ Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

2.1.5.4 Instructions for safe disposal of the product and its packaging

- Do not clean the bait stations or covered bait points between two applications.
- This material and its container must be disposed of in a safe way.
- Do not dispose the product in environment or pipings.
- Dispose of the bait stations and covered bait points in waste reception centres or appropriate collect points.
- The packaging must not be re-used or recycled.
- Unconsumed baits, unused baits, ejected baits outside bait stations and covered bait points and dead rodents must be collected and disposed in waste reception centres or in appropriate collect points.

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

The product can be conserved and used until 2 years after its date of manufacturing.

2.1.6 Other information

The product label and the sachet label have to mention "Do not open the sachet". Authorisation holder should assure the availability of opaque and secured bait stations. Are considered as secure bait stations, boxes in which the bait is inaccessible to children and non-target organisms. Furthermore, a device must be provided to prevent opening by children

Information required post-authorisation

- Provide to the authority in charge of the assessment within 6 months after the date of the decision a compatibility study with claimed packaging (5g paper bag and 50g cartridge).
- Provide to the authority in charge of the assessment within 1 year after the date of the decision the intermediary results of a long-term storage stability study at ambient temperature with the measurements of the content of the active substance in the product. Provide to the authority in charge of the assessment the final results of this study.
- Implement during the authorisation a monitoring in order to report any observed resistance to the product of target species. Report on this issue must be addressed to the authority in charge of the assessment every 2 years after the date of the decision.

2.1.7 Packaging of the biocidal product

The primary packagings of the biocidal product already authorised are:

For non professional users :

BLACK PEARL PASTA is supplied in cartridges (50-100g) to be used with an extrude gun and in individual paper bags of 5-20g packed in

- 100-500g boxes
- 200-500g doypacks
- Prefilled bait boxes

For professional users:

BLACK PEARL PASTA is supplied in cartridges (50-310g) to be used with an extrude gun and in individual paper bags of 5-20g packed in buckets (1-5kg) and prefilled bait boxes.

The new packaging in this modification of packaging dossier are the following ones:

For non professional users :

- Metal can: Up to 1.5Kg
- Metal can + PP bag: Up to 1.5Kg
- Cardboard box: 2 x 10g Bait box (PP or PS)

For professional users:

- Metal cartridge: up to 500g

- Data provided after the request for additional information are indicated in purple and correspond to the new packaging regarding the data provided initially.
- Data indicated in orange correspond to packaging which are not considered in the dossier as there were not included in the first authorisation and they were not indicated in the supporting document

NON PROFESSIONAL USERS:

Primary packaging:

- Sachet of 5g or 10g in tea paper

Secondary packaging:

- Bait box in PS or PP: 10g, 20g

- Bucket PP: 500g, 1Kg, 1.5Kg

- Carton + internal sachet in PP or PE: 40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 360g, 400g, 440g, 480g, 520g, 560g, 1Kg, 1.5Kg

- Carton : 40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 360g, 400g, 440g, 480g, 520g, 560g, 1Kg, 1.5Kg

- Metal box + internal sachet in PP: 40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 360g, 400g, 440g, 480g, 520g, 560g, 1Kg, 1.5Kg

- Metal box: 40g, 80g, 120g, 160g, 200g, 240g, 280g, 320g, 360g, 400g, 440g, 480g, 520g, 560g, 1Kg, 1.5Kg

- Cardboard box with 2 bait box: 10g or 20g.

PROFESSIONAL USERS:

Primary packaging:

- Sachet of 5g or 10g in tea paper

- Cartridge PP: 50g, 100g, 150g, 270g, 310g

- Cartridge aluminium: 50g, 100g, 150g, 170g, 200g

Secondary packaging:

- Bait box in PS or PP: 10g, 20g

- Bucket PP: 5Kg, 6Kg, 7kg, 8Kg, 9Kg, 10Kg, 15Kg, 20Kg

- Carton + internal sachet in PP or PE: 5Kg, 6Kg, 7kg, 8Kg, 9Kg, 10Kg, 15Kg, 20Kg

- Carton : 5Kg, 6Kg, 7kg, 8Kg, 9Kg, 10Kg, 15Kg, 20Kg

The new packagings are acceptable regarding the provided physico-chemical data.

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Identity, physicochemical and analytical method data

New studies have been provided to support the change of packaging: an accelerated storage stability study and validation of the analytical method to determine the active substance in the product.

2.1.8.2 Access to documentation

Please refer to the product assessment report related to BLACK PEARL PASTA product authorisation (FR-2013-1004 for non professional users and FR-2013-0005 for professional users).

2.2 Assessment of the biocidal product

2.2.1 Intended uses as applied for by the applicant

Table 2. Intended use # 1 – Professional users ⁷

Product Type	PT14-Rodenticides
Where relevant, an exact description of the authorised use	The product must be used in rodents control only in tamper-resistant bait stations. Bait stations could be used inside domestic, industrial and commercial buildings including farm buildings in infested areas (along walls, windows...).
Target organism (including development stage)	House mouse (<i>Mus musculus</i>) Adults and juveniles
Field of use	Indoor Stored product protection, food protection, health protection and material protection (ie. historical buildings, technical objects).
Application method(s)	Bait stations and covered bait points could be used inside domestic, industrial and commercial buildings including farm buildings in infested areas (along walls, windows...). The application rate or the number of sachets per bait station and covered bait points must be adapted to the effective rate. The number of bait stations and covered bait points is function of the area of treatment and infestation rate. Distances between bait stations or and covered bait points must be respected. Inspect and refill the bait stations and covered bait points few days after the first application then once in a week as long as the bait is consumed.
Application rate(s) and frequency	Indoor use: - Mice, high infestation: from 5g to 20g of product / bait station or covered bait points. Distance between bait stations or covered bait points: 3 meters. - Mice, low infestation: from 5g to 20g of product / bait station or covered bait points. Distance between bait stations or covered bait points: 5 meters.
Category(ies) of users	Industrial and trained professional
Pack sizes and packaging material	The product BLACK PEARL PASTA is supplied in: - Cartridge, Plastic PP (50, 100 or 310g) - Cartridge, Metal : up to 500g; - Individual sachet in paper (5, 10 or 20g)

Table 3. Intended use # 2 – Non professional users ⁸

Product Type	PT14-Rodenticides
Where relevant, an exact description of the authorised use	The product must be used in rodents control only in tamper-resistant bait stations. Bait stations could be used inside domestic, industrial and commercial buildings including farm buildings in infested areas (along walls, windows...).

⁷ Copy this section as many times as necessary (one table per use).

⁸ Copy this section as many times as necessary (one table per use).

Target organism (including development stage)	House mouse (<i>Mus musculus</i>) Adults and juveniles
Field of use	Indoor Bait stations and covered bait points could be used inside domestic, industrial and commercial buildings including farm buildings in infested areas (along walls, windows...). Aim of use: Stored product protection, food protection, health protection and material protection (ie. historical buildings, technical objects).
Application method(s)	Bait stations and covered bait points could be used inside domestic, industrial and commercial buildings including farm buildings in infested areas (along walls, windows...). The application rate or the number of sachets per bait station and covered bait points must be adapted to the effective rate. The number of bait stations and covered bait points is function of the area of treatment and infestation rate. Distances between bait stations or and covered bait points must be respected. Inspect and refill the bait stations and covered bait points few days after the first application then once in a week as long as the bait is consumed.
Application rate(s) and frequency	Indoor use: - Mice, high infestation: from 5g to 20g of product / bait station or covered bait points. Distance between bait stations or covered bait points: 3 meters. - Mice, low infestation: from 5g to 20g of product / bait station or covered bait points. Distance between bait stations or covered bait points: 5 meters.
Category(ies) of users	Professional and general public
Pack sizes and packaging material	The product BLACK PEARL PASTA is supplied in: <ul style="list-style-type: none"> - individual sachet in paper : 5,10 or 20 g - cartridges (50 or 100g) Sachets in paper are supplied in: <ul style="list-style-type: none"> - prefilled bait boxes - bait boxes (100, 150, 200, 300, 400 or 500g) - doypacks (200 or 500g) - Can /Tin, Metal : up to 1.5 Kg - Can /Tin, Metal + PP bag : up to 1.5Kg - Cardboard boxes: 2 x 10g Bait box (PP or PS)

2.2.2 Physical, chemical and technical properties

Only the new data have been reported in the following table:

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	FR evaluation	Reference		
Storage stability test	CIPAC MT 46 GIFAP Monograph No.	Alpha-chloralose paste bait =	<table border="1"> <tr> <td>Packag</td> <td>Results</td> </tr> </table>	Packag	Results	Acceptable The product is	Richerio ux S. 2015
Packag	Results						

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results		FR evaluation	Reference
– accelerated storage	17 12 weeks at 35°C Packaging material: - Metal box - Metal box+PP bag - Cartridge	Black Pearl Pasta	ing materia l		compatible with the metal box, the PP bag inside a metal box and with the cartridge. No data have been provided on the material of the cartridge as the new packaging is metal cartridge, FR has considered that the tested cartridge in this study corresponds to new packaging	LODI.10 /2015
			Metal box	Black paste in tea paper sachet Fat on the sachets before and after storage Presence of fat on internal wall of the box after storage Weight deviation: <1.6%		
			Metal box+P P bag	Black paste in tea paper sachet Fat on the sachets before and after storage Presence of fat inside the bag after storage Weight deviation: <1.6%		
			Cartridge	No leak at the junction of the different elements. No deformation		

Conclusion on the physical, chemical and technical properties of the product

The product BLACK PEARL PASTA is compatible with the metal box, the PP bag inside a metal box and with the cartridge.

2.2.3 Physical hazards and respective characteristics

Please refer to the product assessment report related to BLACK PEARL PASTA product authorisation (FR-2013-1004 for non professional users and FR-2013-0005 for professional users).

2.2.4 Methods for detection and identification

Please refer to the product assessment report related to BLACK PEARL PASTA product authorisation (FR-2013-1004 for non professional users and FR-2013-0005 for professional users).

2.2.5 Efficacy against target organisms

Please refer to the product assessment report related to BLACK PEARL PASTA product authorisation (FR-2013-1004 for non professional users and FR-2013-0005 for professional users).

2.2.6 Risk assessment for human health

Please refer to the product assessment report related to BLACK PEARL PASTA product authorisation (FR-2013-1004 for non professional users and FR-2013-0005 for professional users).

2.2.7 Risk assessment for animal health

Please refer to the product assessment report related to BLACK PEARL PASTA product authorisation (FR-2013-1004 for non professional users and FR-2013-0005 for professional users).

2.2.8 Risk assessment for the environment

Please refer to the product assessment report related to BLACK PEARL PASTA product authorisation (FR-2013-1004 for non professional users and FR-2013-0005 for professional users).

2.2.9 Measures to protect man, animals and the environment

Please refer to the product assessment report related to BLACK PEARL PASTA product authorisation (FR-2013-1004 for non professional users and FR-2013-0005 for professional users).

2.2.10 Assessment of a combination of biocidal products

Please refer to the product assessment report related to BLACK PEARL PASTA product authorisation (FR-2013-1004 for non professional users and FR-2013-0005 for professional users).

2.2.11 Comparative assessment

Please refer to the product assessment report related to BLACK PEARL PASTA product authorisation (FR-2013-1004 for non professional users and FR-2013-0005 for professional users).

3 ANNEXES⁹

3.1 List of studies for the biocidal product

Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner (PUB / ORG)	Date of first submission
Richerieux S.	2015	Compatibility between Alpha-chloralose paste bait and packagings after accelerated storage 10/2015		LODI	

3.2 Output tables from exposure assessment tools

Please refer to the product assessment report related to BLACK PEARL PASTA product authorisation (FR-2013-1004 for non professional users and FR-2013-0005 for professional users).

3.3 New information on the active substance

Please refer to the product assessment report related to BLACK PEARL PASTA product authorisation (FR-2013-1004 for non professional users and FR-2013-0005 for professional users).

3.4 Residue behaviour

Please refer to the product assessment report related to BLACK PEARL PASTA product authorisation (FR-2013-1004 for non professional users and FR-2013-0005 for professional users).

3.5 Summaries of the efficacy studies (B.5.10.1-xx)¹⁰

Please refer to the product assessment report related to BLACK PEARL PASTA product authorisation (FR-2013-1004 for non professional users and FR-2013-0005 for professional users).

3.6 Confidential annex

Please refer to the product assessment report related to BLACK PEARL PASTA product authorisation (FR-2013-1004 for non professional users and FR-2013-0005 for professional users).

3.7 Other

⁹ When an annex is not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

¹⁰ If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.