Addendum to Product Assessment Report

**Storm Ultra**

January 2024

Addendum to biocidal product assessment report related to product authorisation under Regulation (EU) 528/2012

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# Background

An application for a minor change was received concerning:

1. Removal of co-formulant Luconyl NG Violet from the product composition. Storm Ultra contains another dye and we consider the removal of Luconyl DOES NOT affect the specific conditions (4) of the Regulation (EU) 2017/1383 According to Regulation 354/2013 (Changes Regulation) “Increase or reduction, addition, deletion or replacement of a non-active substance intentionally incorporated in the product” can be considered Minor Changes” where:

— The added or increased non active-substance is not a substance of concern.

— The deletion or reduction of the non-active substance does not lead to an increase of an active substance or a substance of concern.

— The physical-chemical properties and the shelf-life of the product are expected to remain the same.

— The risk and efficacy profile are expected to remain the same.

— A new quantitative risk assessment is not expected to be necessary.

The BAS 322 20 I number for Storm Ultra is changing to BAS 322 26 I.

1. New stability data is provided for Storm Ultra in flexible bags to support an extended shelf-life from 2 years to 3 years.

APCP

The changes proposed as part of the minor change application have been assessed from the physical, chemical and technical point of view and from the information provide it can be concluded that they are acceptable.

Efficacy

The biocidal products have been shown to be sufficiently efficacious against House mice, brown and black rats for the claimed uses with a shelf life of 3 years.

# Decision

1. As part of this request for a minor change the applicant has indicated that the co-formulant Lunonyl NG Violet 5890 is to be removed from the composition of the biocidal product Storm Ultra (BAS 322 20 I). In order to obtain the required 100% mass balance the content of another co-formulant has to be increased. As the content of the co-formulant removed and of the one which is increased does not add up to a change of >10% in the formulation the change is considered acceptable. The old and new composition is included in a confidential addendum.

2. In order to extend the shelf-life of the biocidal product Storm Ultra (BAS 322 20 I) the applicant has performed three stability studies: accelerated storage stability test at 54 °C for 2 weeks (Hopley, W. 2020), long-term stability at ambient temperature for 104 weeks (Hopley, W. 2022/2001346) and long-term stability at ambient temperature for 156 weeks (Hopley, W. 2022/2054635) in PET/PE flexible bags. The flexible bags were stored under compaction during the long term stability study. The physical, chemical and technical characteristics as required by the formulation type were sufficiently addressed in the studies. No significant changes were observed including the content of active ingredient which did not decrease >10% from the initial value. Palatability studies have also been conducted and they indicate that after 3 years of storage the properties of the product are still acceptable. Based on the results of these tests in can be concluded that the shelf-life of 3 years in commercial packaging of the biocidal product Storm Ultra (BAS 322 20 I) is supported. The preexisting information is highlighted in grey while the new information is presented in default text in the table below.

**Physical, chemical, and technical properties of Storm Ultra (BAS 322 20 I) – 25 ppm flocoumafen (nominal)**

| **Numbering according to Annex III of BPR** | **Property** | **Guideline and Method** | **Tested product/batch (AS% w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| 3.1. | Appearance at 20 °C and 101.3 kPa | - | - | - | - |
| 3.1.1. | Physical state at 20 °C and 101.3 kPa | Visual inspection  GLP | BAS 322 20 I (batch: SXE05514/14)  0.0025% w/w flocoumafen )\* | Solid free flowing blocks free from foreign matter. | Weatherhead, P. (2015)  DocID: 2015/1178125  (already accepted in previous authorisation) |
| 3.1.2. | Colour at 20 °C and 101.3 kPa | Visual inspection  GLP | BAS 322 20 I (batch: SXE05514/14)  0.0025% w/w flocoumafen )\* | Blue |
| 3.1.3. | Odour at 20 °C and 101.3 kPa | Organoleptic determination; subjective evaluation by independent persons.  GLP | BAS 322 20 I (batch: SXE05514/14)  0.0025% w/w flocoumafen )\* | Cereal odour |
| 3.2. | Acidity, alkalinity and pH value | CIPAC MT75.3  GLP | BAS 322 20 I (batch: SXE05514/14)  0.0025% w/w flocoumafen )\* | pH 7.1 (1.0% dispersion in deionised water, T= 22.5°C) |
| 3.3. | Relative density / bulk density | CIPAC MT 186  GLP | BAS 322 20 I (batch: SXE05514/14)  0.0025% w/w flocoumafen )\* | Bulk density: 0.49 g/mL  Tap density: 0.52 g/mL |
| 3.4.1.1. | Storage stability test – **accelerated storage** | GLP  CIPAC method MT 46.3  Reg (EU) No 1107/2009 and Reg (EU) No 284/2013  and  Manual on Development and Use of FAO and WHO Specifications for Pesticides, Nov 2010  Storage of the product in semi-opaque 5 kg polypropylene bucket fitted with a push fit lid for 2 weeks at 54 °C.  Examinations:  *A.i. content* (analytical method AFL0199/04 with additional validation MX/15/010/1);  Appearance (method RLA 11803)  Odour (method RLA 12647)  pH value (method CIPAC MT 75.3)  Attrition (CIPAC MT 178)  Pack appearance/weight check (method AGF 0065) | BAS 322 20 I (batch: SXE05514/14)  0.0025% w/w flocoumafen )\* | Stored at 54 °C for two weeks in semi-opaque 5 kg polypropylene bucket fitted with a push fit lid  Content a.s.  Initial: 0.030 g/kg  2 wk, 54 °C: 0.028 g/kg (-6.67 %)  Appearance:  Initial: Blue solid blocks free from foreign matter, free flowing.  After 2 weeks: No change in appearance of the block.  Odour:  Initial: cereal odour  After 2 weeks: No change in odour.  Product is sufficiently stable. |
| GLP  CIPAC method MT 46.3  Reg (EU) No 1107/2009 and Reg (EU) No 284/2013  and  Manual on Development and Use of FAO and WHO Specifications for Pesticides, Nov 2010  Storage of the product in semi-opaque 5 kg polypropylene bucket fitted with a push fit lid for 2 weeks at 54 °C.  Examinations:  *A.i. content* (analytical method AFL0199/04, incorporating additional validation);  Bittering agent content (analytical method AFL0929/01)  Appearance (method RLA 11803.04)  Odour (method RLA 12647.03)  pH value (method CIPAC MT 75.3)  Pack appearance/weight check (method AGF 0065.05) | BAS 322 20 I (batch: 1809022)  0.0025% w/w flocoumafen  Flexible bag:  stand-up pouch made from PET/PE | Stored at 54 °C for two weeks:  Content a.s. %w/w  Initial: 0.00241  2 wk, 54 °C (mean): 0.00236  (-2.07 %)  Content bittering agent %w/w  Initial: 0.00103  2 wk, 54 °C (mean): 0.000863  Appearance:  Initial: Blue, hexagonal solid block, free flowing, no caking or foreign matter present.  After 2 weeks: No change in appearance of the block.  Odour:  Initial: cereal odour  After 2 weeks: No change in odour.  pH:  After 2 weeks: 6.7 (1.0% deionised water)  Pack appearance:  Initial: Flexible bag, no deformation, corrosion, swelling/cracking/crazing of pack walls, visual contamination, external odour, label staining or leakage. Seal integrity was intact.  After 2 weeks: No change, pack as initial.  Weight loss:  After 2 weeks: -1.6 %  Conclusion: The bait was stable when stored at 54 °C for 2 weeks with respect to the active substance and bittering agent content and the physical chemical properties. | Hopley, W. (2020)  DocID: 2020/2001505  Hopley, W. (2020)  DocID: 2020/2036327 |
| 3.4.1.2. | Storage stability test – **long-term storage at ambient temperature** | GLP  method: n.s.,  equivalent to GIFAP monograph no.17  analytical method:  HPLC-UV  Storage of the product in semi-opaque 5 kg polypropylene bucket fitted with a push fit lid under the following conditions:  26 weeks at 25 °C  52 weeks at 25 °C  78 weeks at 25 °C  104 weeks at 25 °C  Examinations:  *A.i. content* (analytical method AFL0199/04 with additional validation MX/15/010/1);  Appearance (method RLA 11803)  Odour (method RLA 12647)  pH value (method CIPAC MT 75.3)  Pack appearance/weight check (method AGF 0065) | BAS 322 20 I (batch: SXE05514/14)  0.0025% w/w flocoumafen )\*  semi-opaque 5 Kg in polypropylene bucket fitted with a push fit lid. | Stored at 104 wks weeks at 25°C  Content a.s.  Initial: 0.030 g/kg  26 wk, 25 °C: 0.030 g/kg  52 wk, 25 °C: 0.029 g/kg  78 wk, 25 °C: 0.030 g/kg  104 wk, 25 °C: 0.029 g/kg (-3.3%)  Appearance:  Initial: Blue solid blocks free from foreign matter, free flowing.  After 26, 52, 78, and 104 weeks: No change in appearance of the block.  Odour:  Initial: cereal odour  After 26, 52, 78, and 104 weeks: No change in odour.  pH:  after 26, 52, 78 and 104 weeks: 5.9 – 7.1  The pH value (1% slurry in water) slightly varied at different time points over storage which has no impact on the stability of the product.  Pack appearance:  Pack was as initial.  Product is sufficiently stable. | Weatherhead, P. (2017)  DocID: 2017/1136269  -terminated after 2 years-  Results already submitted and accepted in previous authorisation |
| GLP  according to Regulation (EU) 1107/2009 as set out in Regulation (EU) 284/2013  analytical method:  HPLC-UV  Storage of the product in flexible bags (stand-up pouches made from PET/PE) under the following conditions:  52 weeks at 25 °C  104 weeks at 25 °C  156 weeks at 25 °C  Packaging conditions: 40 bags were packed in a carton. Each carton consisted of a bottom layer of 4 bags (bags under compaction, bags 2, 3, 4 and 5) and on top of these bags 9 layers of 4 bags were packed. Bag 1 was on top. without compaction.  This set-up is equivalent to the situation in practice where for sales a carton of the same size is used,  containing 40 bags packed in 10 layers of 4 bags each.  Examinations:  *A.i. content* (analytical method AFL0199/04);  Bittering agent content (analytical method AFL0929/01)  Appearance (method RLA 11803.04)  Odour (method RLA 12647.03)  pH value (method CIPAC MT 75.3)  Pack appearance/weight check (method AGF 0065.05) | BAS 322 20 I (batch: 1809022)  0.0025% w/w flocoumafen  Flexible bag:  stand-up pouch made from PET/PE | Stored at 156 weeks at 25°C  Content a.s. %w/w  Initial: 0.00241  52 wk, 25 °C: 0.00238  104 wk, 25 °C: 0.00255  156 wk, 25 °C: 0.00241  (mean of 2 replicates)  (0 %)  Content bittering agent %w/w  Initial: 0.00103  52 wk, 25 °C: 0.00106  104 wk, 25 °C: 0.00096  156 wk, 25 °C: 0.00080  (mean of 6 replicates with each 2 injections)  Appearance:  Initial: Blue, hexagonal solid block, free flowing, no caking or foreign matter present.  After 52, 104, and 156 weeks: No change in appearance of the block (either under compaction or not).  Odour:  Initial: cereal odour  After 52, 104, and 156 weeks: No change in odour.  pH (1.0% deionised water):  After 52, 104, and 156 weeks: 6.4-6.6  Pack appearance:  Initial: flexible bag, no deformation, corrosion, swelling/cracking/crazing, visual contamination, external odour, label staining or leakage. Seal integrity was intact.  After 156 weeks: Pack was as initial.  Weight loss:  52 wk, 25 °C: 1.5%  104 wk, 25 °C: 2.1-2.6%  156 wk, 25 °C: 2.7-3.2%  *The product loss of weight can be explained by two factors. Firstly, the soft pouches used for the study consisted of a material that is semi-resistant to diffusion. Thus, over time there would be an exchange of gaseous components (e.g. water vapour) between the surrounding environment and the contents of the soft pouches. The majority of the product formulation consists of natural ingredients such as cut wheat, which each have an equilibrium moisture content based on the climatic conditions of the surrounding environment (in the case of this study the air around the product in the flexible bag). If the humidity of the air outside the flexible bags is lower than that inside, vapour diffuses through the flexible bag, the equilibrium inside the bag is disturbed, the blocks then release moisture. This release of moisture results in a weight loss which is measurable.*  *The second factor is that the binder within the product is hardening by water release and not by a chemical polymerization. Both of these factors can explain the minor weight loss observed. In addition, it should be noted that all physical, chemical and biological parameters were not altered and fully met the requirements.*  Conclusion: The bait was stable when stored at 25°C for 156 weeks with respect to the active substance and bittering agent content and the physical chemical properties. | Hopley, W. (2022)  DocID: 2022/2001346  Hopley, W. (2022)  DocID: 2022/2054635 |
| HPLC in-house method | BAS 322 05 I  Batch number:  0021742369 | Supportive information:  OPP content in Storm products after 3 years: 0.0453 % (corresponding to 453 ppm)  Conclusion:  The OPP content does not increase over 3 year storage. | Oyinlade, K. (2023) |
| **eCA remark:** In order to address the possible change in content of the identified SoC, OPP, the applicant has provided supportive information on the content of this substance determined in the product after storage for 3 years at 25 °C. The quality of this study report is not considered acceptable however, the eCA considers that no further information is required as it is not expected that the content of OPP will change significantly during storage. | | | | | |
| 3.4.1.3. | Storage stability test – **low temperature stability test for liquids** |  |  | Not applicable as the product is a solid bait and not a liquid. | (already accepted in previous authorisation) |
| 3.4.2.1. | Effects on content of the active substance and technical characteristics of the biocidal product – **light** |  |  | Not applicable as the product is stored in non-transparent containers and/or are not expected to be exposed to light.  The packages described as ‘semi-opaque’ in the storage stability studies, have an opaqueness of 19.6 (10kg packages), 16.6 (5 kg packages), 13.1 (3 kg packages) or 33.5 (300 g packages). The two smallest packages are further packed in cardboard during transport. Hence, exposure to light is limited and the sentence ‘Protect from direct sunlight’ is sufficient. | (already accepted in previous authorisation) |
| 3.4.2.2. | Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | Humidity:  Submission of data on effects of humidity is not required as the packaging precludes moisture.  Effects on temperature: see below. |  |
| GLP  Examinations:  *A.i. content* (analytical method AFL0199/04 with additional validation MX/15/010/1);  Appearance (method RLA 11803)  Odour (method RLA 12647)  pH value (method CIPAC MT 75.3)  Attrition (CIPAC MT 178)  Pack appearance/weight check (method AGF 0065) | BAS 322 20 I (batch: SXE05514/14)  0.0025% w/w flocoumafen )\*  in a polypropylene bucket | Stored at 54 °C for two weeks  Product is sufficiently stable. | Weatherhead, P. (2015)  Doc-ID: 2015/1178125  (already accepted in previous authorisation) |
| 3.4.2.3. | Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | GLP  Pack appearance/weight check (method AGF 0065) | BAS 322 20 I (batch: SXE05514/14)  0.0025% w/w flocoumafen )\* | Stored at 54 °C for two weeks in a polypropylene bucket  Packaging material was found to be unchanged compared to initial in all samples. | Weatherhead, P. (2015)  Doc-ID: 2015/1178125  (already accepted in previous authorisation) |
| GLP  Pack appearance/weight check (method AGF 0065) | BAS 322 20 I (batch: SXE05514/14)  0.0025% w/w flocoumafen )\* | Stored in polypropylene bucket for 104 weeks at 25 °C.  Packaging material was found to be unchanged compared to initial in all samples. | Weatherhead, P. (2017)  DocID: 2017/1136269  104wks  (already accepted in previous authorisation) |
| GLP  Pack appearance/weight check (method AGF 0065.05) | BAS 322 20 I (batch: 1809022)  0.0025% w/w flocoumafen  Flexible bag:  stand-up pouch made from PET/PE | Stored at 54 °C for two weeks  Packaging material was found to be unchanged compared to initial in all samples. | Hopley, W. (2020)  DocID: 2020/2001505 |
| GLP  Pack appearance/weight check (method AGF 0065.05) | BAS 322 20 I (batch: 1809022)  0.0025% w/w flocoumafen  Flexible bag:  stand-up pouch made from PET/PE | Stored 104 and 156 weeks at 25°C.  Packaging material was found to be unchanged compared to initial in all samples. | Hopley, W. (2022)  DocID: 2022/2001346  Hopley, W. (2022)  DocID: 2022/2054635 |
| 3.5.1. | Wettability |  |  | Not required since the product is a ready for use solid bait. | (already accepted in previous authorisation) |
| 3.5.2. | Suspensibility, spontaneity, and dispersion stability |  |  | Not required since the product is a ready for use solid bait. | (already accepted in previous authorisation) |
| 3.5.3. | Wet sieve analysis and dry sieve test |  |  | Not required since the product is a ready for use solid bait. | (already accepted in previous authorisation) |
| 3.5.4. | Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not required since the product is a ready for use solid bait. | (already accepted in previous authorisation) |
| 3.5.5. | Disintegration time |  |  | Not required since the product is a ready for use solid bait. | (already accepted in previous authorisation) |
| 3.5.6. | Particle size distribution, content of dust/fines, attrition, friability |  |  | Particle size distribution, content of dust/fines:  Not required since the product is a ready for use solid bait block and not a powder or granule. |  |
| CIPAC MT178  GLP | BAS 322 20 I (batch: SXE05514/14)  0.0025% w/w flocoumafen )\* | Attrition, friability:  Attrition resistance: 100% | Weatherhead, P. (2015)  Doc-ID: 2015/1178125  (already accepted in previous authorisation) |
| 3.5.7. | Persistent foaming |  |  | Not applicable as the product is a solid bait. | (already accepted in previous authorisation) |
| 3.5.8. | Flowability/pourability/dustability |  |  | Not applicable as the product is a solid bait. | (already accepted in previous authorisation) |
| 3.5.9. | Burning rate — smoke generators |  |  | Not applicable as the product is a ready for use bait and not a smoke generator. | (already accepted in previous authorisation) |
| 3.5.10. | Burning completeness — smoke generators |  |  | Not applicable as the product is a ready for use bait and not a smoke generator. | (already accepted in previous authorisation) |
| 3.5.11. | Composition of smoke — smoke generators |  |  | Not applicable as the product is a ready for use bait and not a smoke generator. | (already accepted in previous authorisation) |
| 3.5.12. | Spraying pattern — aerosols / spray |  |  | Not applicable as the product is a ready for use solid bait block and not an aerosol. | (already accepted in previous authorisation) |
| 3.6.1. | Physical compatibility |  |  | Not applicable as the product is a ready for use bait and not intended to be mixed with other products. | (already accepted in previous authorisation) |
| 3.6.2. | Chemical compatibility |  |  | Not applicable as the product is a ready for use bait and not intended to be mixed with other products. | (already accepted in previous authorisation) |
| 3.7. | Degree of dissolution and dilution stability |  |  | Not applicable as the product is a ready for use solid bait and not intended to be dissolved. | (already accepted in previous authorisation) |
| 3.8. | Surface tension |  |  | Not applicable as the product is a ready for use bait not intended to be dispersed in water. | (already accepted in previous authorisation) |
| 3.9. | Viscosity |  |  | Not applicable as the product is a ready for use solid bait. | (already accepted in previous authorisation) |

)\* the content was determined in the frame of the study as 0.03 g/kg (before storage).

**Efficacy data**

To be able to authorise a shelf life of 3 years, 3 new palatability studies were conducted with 36-months aged product with House mice, black rats and brown rats.

These studies are not performed with the new product composition included in this minor change application. However, the new product composition is considered to have no influence on the palatability of the product as the only change is the removal of one of the two blue dyes. The product still contains a blue dye and the colour will change only slightly if at all. The blue dye is merely required to prevent non-target primary exposure and as a warning dye and has no influence on mice and rats. Therefore, the eCA considers the provided studies sufficiently reliable to reflect the efficacy of the new product composition.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| PT and use number | Test product | Function / Test organism(s) | **Test method / Test system / concentrations applied / exposure time** | Test results: effects | Reference |
| **Black rat (*Rattus rattus*)** | | | | | |
| PT 14  Indoor Outdoor around buildings, use numbers 2,3,5,6,7,8 | RB Bait  Storm Ultra Block Rodenticide Bait (BAS 322 20 I)  0.0025 % (w/w) flocoumafen  36 months stored bait (5 g block size). | Black rat (*Rattus rattus*)  Wild derived  2 subpopulations (5 males/5 females)  Three test pens (each measuring 69 x 60 x 58 cm, L x W x H) consisting of white polypropylene and were connected by stainless-steel tunnels. All pens contained bedding, pen 1 contained a shelter, pen 3 contained the feeding bowls. Control diet and water was available at libitum. | **Laboratory test (choice feeding, aged bait)**  Pre-treatment: 7-day acclimatisation period, 3 d pre-test diet take assessment;  Treatment period:10 d choice feeding period;   * 1 test bait point, 100 g (20 blocks, secured) of test item, refilling took place on day 3, day 7 and 14. * Control diet and water ad libitum   At the conclusion of the choice feeding period, the rats were maintained for a further 14-day period with food and tap water available *ad libitum.* The rats were observed at least once a day and any toxic signs and mortality recorded. | Mean diet take: 19.1 g or 11.5 g (males and females, respectively.  Palatability ratios were 2.35 (range 0.41 - 3.57) and 3.00 (range 0.57 - 3.42) in male and female rats, respectively.  **100 % mortality** was effected. The mean times to death were 6.8 (range 5-8) days and 8.6 (range 6-10) days for the males and females, respectively.  The test is considered to be valid with regards to the intended use and according to principles set in Guidance on the BPR: Volume II Parts B+C (2018). | Richter D. (2018)  BASF DocID: 2023/2049684 |
| **Brown rat (*Rattus norvegicus*)** | | | | | |
| PT 14  Indoor Outdoor around buildings, use numbers 2,3,5,6,7,8 | BAS 322 20 I  0.0025 % (w/w) flocoumafen  36-months aged bait in flexible bags. | Brown rat (*Rattus norvegicus*)  Wistar Han strain  5 females and 5 males  individual caged in polypropylene cages 40.0 x 25.0 x 20.0 cm (l x w x h) with stainless steel wire mesh lid and base, over a tray containing a paper liner. | **Laboratory test (choice feeding, aged bait)**  Pre-treatment: Acclimatisation period of 3 days in individual cage at room temperature, which included a 24h pre-test diet take assessment.  Treatment period:4 days, control diet and test item (pre-treated by ageing for 36 months at ambient temperature n flexible bags) were given:   * 50 g per animal of reference food for the assessment of palatability, * 50 g per animal of test item during 4 consecutive days with daily consumption measurements. * Test bait and control diet were replaced daily with freshly treated bait and fresh control diet.   At the conclusion of the choice feeding period, the rats were maintained for a further 14-day period with food and tap water available *ad libitum.* The rats were observed at least once a day and any toxic signs and mortality recorded. | Palatability ratio= **0.49**  Mortality = 100 **%**  The mean times to death were 7.3 (range 5-14) days.  The test is considered to be valid according to principles set in Guidance on the BPR: Volume II Parts B+C (2022). | Richter, D., 2022  BASF DocID:  2022/2053956 |
| **House mouse (*Mus musculus*)** | | | | | |
| PT 14  Indoor Outdoor around buildings, use numbers 2,3,5,6,7,8 | BAS 322 20 I  0.0025 % (w/w) flocoumafen  36-months aged bait in flexible bags. | House mouse (*Mus musculus*)  Horst strain (wild derived)  6 females and 6 males | **Semi-field (choice feeding pen trial) test**  Pre-treatment 7 days subpopulation of 12 individuals caged in a test pen (measuring 69 x 60 x 58 cm (l x w x h) consisting of white polypropylene. The pen contained bedding, 2 shelters and a bridge made from stainless-steel mesh on which metal feed container may be fastened.  Pre-treatment: Acclimatisation period of 7 days followed by a 3 day pre-census period.  Treatment period: control diet and bait have been given:   * 250 g of control diet, * 24 g (1 blocks) of test item with bait replenished on days 3, 7, 14.   Mortality was observed during 21 days (test period) and 14 days post treatment observation every 24 hours | Mortality = **100 %** mortality by day 10 of the bait treatment period  Mean time to death = 6.3 (range 4-10) days  The Days 1 + 2 and Day 4 palatability ratios recorded for the rodenticide bait were 0.43 and 4.32, respectively. The mean palatability ratio throughout the test period was 3.86.  The test is considered to be valid according to principles set in Guidance on the BPR: Volume II Parts B+C (2022). | Richter, D., 2022  BASF DocID:  2022/2054439 |

The newly submitted efficacy studies of 36-month aged Storm Ultra baits show sufficient efficacy against *Rattus norvegicus, Rattus rattus* and *Mus musculus* in choice feeding trials.

**Conclusion on efficacy**

Storm Ultra is palatable for *Rattus norvegicus*, *Rattus rattus* and *Mus musculus* and causes mortality as required for satisfactory control of rodent infestations after 36 months of storage. The current label claims remain supported and shelf-life is extended to 3 years.