

## SAFETY DATA SHEET

Prepared in accordance with Regulation (EC) No 1907/2006 as amended by Regulation (EU) No 2020/878

### Section 1: Identification of the mixture and of the company/undertaking

- 1.1. Product identifier: RATEX pellet bait**  
UFI-code: GT10-407U-G00F-RKUG
- 1.2 Relevant identified uses of the mixture and uses advised against:**  
**Biocidal product, product type PT14.**  
Rodenticides (products used to control mice, rats and other rodents, excluding repellents and attractants)  
**Marketing category: III. – for general-, professional-, and trained professional users.**  
**Contraindicated uses:** Uses other than those listed above.
- 1.3. A Manufacturer and safety data sheet supplier details:**  
**METATOX Peszticid Gyártó- és Forgalmazó Kft.**  
H-5520 Szeghalom, Kossuth u. 8.  
Telephone: +3666 371 168  
**Contact details of the person responsible for the safety data sheet:** [info@metatox.hu](mailto:info@metatox.hu)
- 1.4. Emergency phone number: Health Toxicological Information Service**  
Egészségügyi Toxikológia Tájékoztató Szolgálat (ETTSZ):  
Daytime, for normal fee (8:00-16:00): +361 476 6464  
0-24 hours, free of charge: +3680 20 1199


### Section 2: Hazards identification

**2.1. Classification of the mixture:** according to the manufacturer, the relevant EU regulations, Regulation (EC) No. 1272/2008 and its amendments, **the product is a hazardous mixture.**

Classification	Hazard class	Hazard category
Health hazard	STOT RE 2 Specific target organ toxicity, repeated exposure	2

**Physical hazard, environmental hazard:** the product is not classified.

**2.2. Labeling elements**  
**Pictogram:** GHS08      **Warning:** DANGER

<b>DANGER</b> 	<b>Hazard statements:</b> H373 Causes damage to organs through prolonged or repeated exposure (blood). <b>Precautionary statements:</b> P101 If medical advice is needed, have product container or label at hand. P102 Keep out of reach of children. P270 Do not eat, drink or smoke when using this product. P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. P401 Keep away from food, drink and animal feeding stuffs.. P501 Dispose of contents/container to according to the local regulations.
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**Biocidal active ingredient content:** 0.0025% Bromadiolone

**Notes:** Biocidal product, must be packaged/labeled in accordance with Regulation (EU) No 528/2012 of 22 May 2012 on the placing on the market and use of biocidal products.

**2.3. Other hazards:** The active ingredient of the product is an anticoagulant, if large quantities are swallowed, blood clotting disorders, bleeding disorders, internal bleeding may occur. The rodenticide contains a bitter substance (denatonium benzoate), which helps prevent accidental human consumption of the product.

To prevent public health hazards and secondary poisoning, rodents that die during treatment should be removed. Dead rodents should be collected using protective gloves, an inverted plastic bag, then placed in a second bag and tied tightly. The carcass in the double bag should be placed in a closed waste container; further treatment should be as municipal waste, see also section 13.

The product has no other known special hazards for humans or the environment. The active substance in the mixture, bromadiolone, is classified as a PBT substance. For further information on **PBT and vPvB assessment**, see section 12.

**Endocrine-disrupting properties:** Based on the available data, it does not contain any endocrine disruptors or endocrine disrupting substances.

## Section 3: Composition / information on ingredients

**3.1. Substances:** not relevant.

**3.2. Mixtures:** the product is mixture.

Hazardous component	Concentration	Classification according to Regulation (EC) No 1272/2008 (CLP)
Bromadiolone* CAS-nr: 28772-56-7 EC-nr: 249-205-9 Index-nr: 607-716-008	0,0025%	Acute Tox. 1 (oral, dermal, inhal.), H300, H310, H330; Repr. 1B, H360D, STOT RE 1, H372 (vér) Aquatic Acute 1, H400, M <sub>(acute)</sub> : 1; Aquatic Chronic 1, H410, M <sub>(chronic)</sub> : 1 Individual concentration limits: if the concentration is $\geq 0,003\%$ , then Repr. 1B, H360D, if the concentration is $\geq 0,005\%$ , then STOT RE 1, H372 if $0,0005\% \leq \text{concentration} < 0,005\%$ , then STOT RE 2, H373
Denatonium-benzoate** CAS-nr: 3734-33-6 EC-nr: 223-095-2	0,001%	Acute Tox. 4 (oral, inhal.), H302, H332; Skin Irrit. 2, H315; Eye Dam. 1, H318; Aquatic Chronic 3, H412

\* Chemical name: 3-[(1RS,3RS;1RS,3SR)-3-(4'-brómbifenil-4-il)-3-hidroxi-1-fenilpropil]-4-hidroxikumarin

\*\* no harmonised EU classification, according to the manufacturer's data provided

Other unlabeled components are not considered hazardous substances according to the applicable legislation, or their concentration in the preparation does not reach the level above which their presence must be taken into account for hazard classification.

The above hazard classes, categories and H-phrases apply to the pure component, the hazard classification of the preparation is given in Section 2.

For the full text of the H-phrases and the meaning of abbreviations, see Section 16.

## Section 4: First aid measures

### 4.1. Description of first aid measures

**General information:** Professional and rapid first aid can greatly reduce the onset and severity of symptoms. Do not give fluids to an unconscious or convulsive patient or induce vomiting!



**In case of inhalation:** inhalation of the product is not a life-threatening exposure; standard measures: move the injured person to fresh air, if symptoms or poisoning are suspected, consult a doctor!

**In case of skin contact:** wash the affected skin area thoroughly with soap and plenty of water. If irritation occurs, consult a doctor.

**In case of eye contact:** immediately rinse the eyes with plenty of water for at least 10 minutes while holding the eyelids apart and moving the eyeball. If contact lenses are present, remove them and continue rinsing. If symptoms persist, consult a specialist.

**In case of ingestion:** if swallowed, consult a doctor IMMEDIATELY and show the product box, label or safety data sheet. Induce vomiting only if specifically instructed to do so by a doctor!

Rinse the mouth with water.

**4.2. Most important symptoms and effects, both acute and delayed:** the active ingredient of the product is the anticoagulant bromadiolone. After ingestion of the product, the blood's ability to clot decreases, internal bleeding may occur. It may take several days between poisoning and the appearance of symptoms.

**4.3. Indication of any immediate medical attention and special treatment needed:** when treating a poisoned person who has swallowed the product, if typical symptoms (e.g. nosebleeds, bleeding gums, in severe cases, spitting up blood, bloody urine, prolonged blood clotting time, large or multiple hematomas, sudden, unusual visceral pain) are observed, administer vitamin K1. If no bleeding is observed, measure prothrombin activity (INR) and repeat the measurement 48–72 hours after exposure.

If the prothrombin activity value is  $>4$ , the poisoned person should be given vitamin K1 intravenously. The treatment may need to be repeated several times.

**Note to the physician:** The active ingredient of the product is a coumarin anticoagulant, the **antidote is vitamin K1**.

Prothrombin activity should be monitored for several days, especially if a larger amount of rodenticide has entered the body.

## Section 5: Firefighting measures

The product is not flammable, but is combustible.

**5.1. Suitable extinguishing media:** standard extinguishing media: carbon dioxide, dry chemical, water spray, foam.

It is advisable to select based on the materials burning in the environment.

**Unsuitable extinguishing media:** high-pressure water jet.

**5.2. Special hazards arising from the mixture:** under the influence of high temperatures, toxic and irritating gases and vapours may be released during combustion and decomposition, e.g. carbon monoxide, carbon dioxide.

**5.3. Advice for fire-fighters:** full protective equipment and self-contained breathing apparatus are required if there is a risk of exposure to fumes or combustion products.

## Section 6: Accidental release measures

**6.1. Personal precautions, protective equipment and emergency procedures:**

Mechanically collect spilled product, wear protective gloves and avoid exposure to the product! In case of large quantities, the use of a dust mask is recommended.

**6.1.1. For non-emergency personnel:** notify authorities to remove unauthorized persons.

**6.1.2. For emergency responders:** personal protective equipment is required. Release should only be performed by a trained person.



**6.2. Environmental precautions:** Do not allow spilled product to enter drains, water bodies or soil! Dispose of in accordance with local regulations. If the product enters drains or water bodies, notify the Disaster Management Directorate.

**6.3. Methods and materials for containment and cleaning up:** Sweep up spilled product mechanically and as far as possible without residue or dust, place in suitable containers and dispose of. Dispose of in accordance with local regulations by a licensed hazardous waste disposal company. Wash contaminated area with water or water containing detergent.

**6.4. Reference to other sections:** see also sections 8 and 13.

## Section 7: Handling and storage

### 7.1. Precautions for safe handling:

The product is for rodent control only and should only be used as directed in the instructions for use! Before using the product, read and follow the product information on the label, as well as the product description, leaflet, etc. attached to the product or given at the time of sale. Work carefully to avoid exposure to the product: skin contact, eye contact and ingestion. Do not eat, drink or smoke during application! Contaminated clothing and protective equipment must be removed when entering an area where people eat. After handling, wash hands thoroughly with soap.

### 7.2. Conditions for safe storage, including any incompatibilities:

The product should be stored in its original packaging, in a dry, cool, well-ventilated place, away from direct sunlight, moisture, and away from food, drink, feed and incompatible materials. Keep the product out of reach of children, unauthorized persons, birds, farm animals and pets. Shelf life: If stored properly, it will retain its quality for 2 years from the date of manufacture.

**7.3. Specific end use(s):** biocidal product, for general use. Users should always read the instructions for use and follow the instructions for safe handling and use.

## Section 8: Exposure controls / personal protection

### 8.1. Control parameters

**Occupational exposure limit values (Commission Directive (EC) No 2000/39 of 8 June 2000):** permissible value in the workplace air: not established for the components of the product. Periodic medical examination is recommended for professional users, as repeated undesirable exposure to the product may reduce the blood's ability to coagulate.

### 8.2. Exposure controls

**Technical measure:** not required.

#### Hygiene measures:

- Eating, drinking and smoking are not allowed while working!
- After application, wash hands thoroughly with warm, soapy water.
- Do not get on clothing or skin.

#### Personal protective equipment

- **Respiratory protection:** not required.
- **Hand protection:** It is recommended to wear household rubber gloves when using. In case of prolonged repeated exposure and/or when applying the pesticide, chemical-resistant protective gloves complying with EN 374 are required. Replace the protective gloves if damaged. When selecting the glove material, pay attention not only to the material but also to the quality indicators, as they vary from manufacturer to manufacturer. The selection should take into account the breakthrough time, the degradation parameters, as well as workplace factors such as duration of use, frequency, other chemicals with which there is a risk of contact, physical requirements (cut/puncture protection).



- **Eye protection:** not required.
- **Skin protection:** working clothes.

### Environmental measures

To avoid secondary infections, the product should be placed in a place where pets, farm animals, birds and non-target organisms cannot reach it. Pets and all other predatory and/or scavenging non-target organisms may be poisoned if they consume rodents killed by the rodenticide.

Do not allow the product and its packaging to enter drains or water bodies!

The above applies to activities performed professionally and under intended conditions of use, under what can be considered average circumstances. If work is carried out under different conditions or extraordinary circumstances, it is recommended to decide on further necessary actions and personal protective equipment with the involvement of an expert.

## Section 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state:	solid
Appearance:	pellets 5-15 mm long, 6 mm diameter
Colour:	red
Taste:	bitter (contains denatonium benzoate)
Odour:	neutral
Odour threshold:	not relevant
pH value at 20°C:	6.6 ± 0.1 (1% aqueous suspension)
Vacuum density at 20°C:	0.576±0.011 g/cm <sup>3</sup>
Melting/boiling point:	not relevant
Decomposition temperature:	no data
Flash point:	not relevant
Auto-ignition temperature:	no data
Flammability (gas, solid):	not flammable
Vapour pressure:	no data
Evaporation rate:	not relevant
Solubility in water:	suspendible
Partition coefficient:	not relevant, the product is a mixture
Viscosity:	not relevant
Explosive properties:	not typical, no explosion hazard
Explosive limits:	not relevant
Oxidizing properties:	not oxidizing

### 9.2. Other information

**Information on physical hazard classes:** based on the available data, the product is not classified into physical hazard classes.

**Other safety features:** none whose indication is essential for the safe use of the mixture.

## Section 10: Stability and reactivity

**10.1. Reactivity:** not relevant.

**10.2. Chemical stability:** Under normal conditions (standard temperature and pressure conditions and the storage conditions specified in section 7), the product is stable..

**10.3. Possibility of hazardous reactions:** not known.

**10.4. Conditions to avoid:** high temperature, heat, heating, frost, moisture.

**10.5. Incompatible materials:** strong acids, alkalis, oxidizing agents.



**10.6. Hazardous decomposition products:** not available under normal conditions. In case of fire, toxic and irritating gases and vapours are formed, see section 5.

## Section 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008:

**Acute toxicity (oral, dermal, inhalation):** Based on the estimated  $ATE_{mix}$  values, the product is not classified as an acute toxicity hazard class.

Measured acute oral  $LD_{50}$  (rat): >2000 mg/kg bw, OECD 423

Measured dermal  $LD_{50}$  (rabbit): >2000 mg/kg bw.

Does not irritate eyes or skin. Does not cause sensitization.

**Skin corrosion/irritation:** based on the composition of the product and the available data, it is not corrosive and does not irritate the skin.

**Serious eye damage/eye irritation:** based on the composition of the product and the available data, it does not cause serious eye damage or irritate the eyes.

**Respiratory and skin sensitization:** the product does not cause sensitization.

**Germ cell mutagenicity:** based on the available data and information, the product is not classified as a mutagenic mixture.

**Carcinogenicity:** based on the available data and information, the product is not classified as a carcinogenic mixture.

**Reproductive toxicity:** based on the specific concentration limit established for bromadiolone, the classification criteria are met, the product is a mixture that is toxic to reproduction (Repr. 1B); may cause harm to the unborn child.

**Specific target organ toxicity, single exposure/STOT SE:** the product is not classified as a STOT SE hazard class, the criteria for classification in this hazard class are not met.

**Specific target organ toxicity, repeated exposure/STOT RE:** the criteria for classification in this hazard class are met based on the individual concentration limit established for bromadiolone, since the concentration of bromadiolone in the product is 0.0025%, the product is classified as a STOT RE 1 hazard class.

**Aspiration toxicity:** the product is not classified as a mixture presenting an aspiration toxicity hazard.

### 11.2. Information on other hazards

Product containing a second-generation anticoagulant active ingredient, the active ingredient content in the products is so low that the toxic dose for a person of normal body weight is several kilograms, and the probability of consuming it is very low due to the bitter substance in the product.

Poisoning caused by second-generation anticoagulants can be easily treated by administering vitamin K1 and measuring the blood clotting factor. In case of ingestion of large quantities, blood clotting disorders may occur, the blood's ability to clot may decrease, bleeding tendency, and internal bleeding may develop.

Repeated undesirable exposure to the product may reduce the blood's ability to clot, see also sections 4.2 and 4.3.

**Endocrine disruption:** Based on the available data, the mixture does not contain substances that cause endocrine disorders or damage the endocrine system.

## Section 12: Ecological information

**12.1. Toxicity:** Bromadiolone is very toxic to aquatic organisms and causes long-term damage, but the product itself is not classified as a mixture hazardous to the aquatic environment, since the concentration of bromadiolone in the product is only 0.0025% and the acute and chronic M-factor for bromadiolone is 1.

**Bromadiolone (ISO) (CAS: 28772-56-7):**

$LC_{50}$  (*Oncorhynchus mykiss*): 1.4 mg/l/96 hours



LC<sub>50</sub> (*Lepomis macrochirus*): 3.0 mg/l/96 hours  
EC<sub>50</sub> (*daphnia*): 5.8 mg/l/48 hours

**12.2. Persistence and degradability:** Bromadiolone is difficult to biodegrade and is hydrolytically stable.

**12.3. Bioaccumulative potential:** bromadiolone is bioaccumulative: its bioconcentration factor and partition coefficient are high.

**12.4. Mobility in soil:** bromadiolone is not mobile or slightly mobile based on the K<sub>oc</sub> value.

**12.5. The results of the PBT and vPvB assessment:** bromadiolone is a PBT (persistent, bioaccumulative and toxic) and a potential vPvB (very persistent and very bioaccumulative) substance.

It has also been experimentally proven that bromadiolone is a bioaccumulative and very bioaccumulative compound.

**12.6. Endocrine disrupting properties: bromadiolone has not been identified as an endocrine disruptor<sup>1</sup>.**

*Opinion on the application for renewal of the approval of bromadiolone (ECHA/BPC/111/2016)* <https://echa.europa.eu/documents/10162/06ef03f0-2b42-453a-9fc1-cc3b667465c9>

**12.7. Other adverse effects, information:** Avoid release of product residues and packaging into soil, water bodies or drains. Primary and secondary exposure of non-target animals and the environment should be minimised by risk mitigation measures.

## Section 13: Disposal considerations

The guidelines for the management of residues and waste of the preparation are set out in Government Decree 225/2015 (VIII.7.), and for the management of packaging waste, in Government Decree 442/2012 (XII. 29.).

After treatment, remove the feeding areas and collect the remaining pesticide, as well as the rodent control equipment and bait stations.

Any spilled pesticide must be cleaned up.

Pesticides that cannot be used for their original purpose and have become waste must be treated as hazardous waste and taken to a hazardous waste collection point – e.g. a waste yard.

**The waste classification of the product was based on Decree 72/2013. (VIII. 27.) of the Minister of the Interior.**

Waste classification of the preparation (Waste code/EWC code):

07 04 wastes from the manufacture, formulation, supply and use of organic pesticides (except 02 01 08 and 02 01 09), wood preservatives and biocides

07 04 13\* solid waste containing hazardous substances

## Section 14: Transport information

The preparation is **not a dangerous good according to the** conventions regulating the international transport of dangerous goods – **ADR/RID, IMDG and IATA.**

**14.1. UN-nr or identification nr.:** not relevant.

**14.2. UN proper shipping name:** not relevant.

**14.3. Transport hazard class(es):** not relevant.

**14.4. Packing group:** not relevant.

**14.5. Environmental hazards:** not relevant.



**14.6. Special precautions for user:** not relevant.

**14.7. Maritime transport in bulk according to IMO instruments:** not relevant.

## Section 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

The approval of the active substance bromadiolone for use in rodenticides (Directive 2009/92/EC) was renewed by Regulation 2017/1380/EU. The product does not contain a substance listed in Annex XIV or XVII of REACH. The product does not contain a substance on the SVHC candidate list.

#### Relevant Community legislation

Biocide Regulation: 528/2012/EU and its amendments  
REACH Regulation: 1907/2006/EC and its amendments  
CLP Regulation: 1272/2008/EC and its amendments  
Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

#### Relevant national legislation

Biocide: Government Decree 316/2013 (VIII.28.) on certain rules for the authorisation and placing on the market of biocidal products;  
Occupational safety: Act XCIII of 1993 on occupational safety; Decree 5/2020 (II. 6.) of the Ministry of the Interior on the protection of the health and safety of workers exposed to chemical pathogens; Decree 33/1998 (VI.24.) of the Ministry of the Interior on the medical examination and assessment of occupational, professional and personal hygiene suitability; Joint Decree 3/2002 (II.8.) of the Ministry of the Interior and the Ministry of the Interior on the minimum level of occupational safety requirements for workplaces;  
Chemical safety: Act XXV of 2000 on Chemical Safety and its amendments, Decree 44/2000. (XII.27.) of the Ministry of Health and Welfare on the detailed rules of certain procedures and activities related to hazardous substances and hazardous preparations and its amendments;  
Environmental protection: Act LIII of 1995 on general rules for environmental protection; Act CLXXXV of 2012 on waste; Government Decree 225/2015 (VIII.7.) on detailed rules for certain activities related to hazardous waste; Decree 72/2013 (VIII.27.) of the Ministry of the Environment on the list of waste;  
Fire protection: Act XXXI of 1996 on fire protection, technical rescue and the fire brigade; Decree 54/2014. (XII.5.) of the Ministry of the Interior on the National Fire Protection Regulations.

**15.2. Chemical safety assessment:** not carried out.

## Section 16: Other information

The safety data sheet is not intended to guarantee any specific properties of the product and does not replace the product specification.

The information, data and recommendations contained in this safety data sheet are based on the best of our knowledge and understanding and are believed to be accurate and correct at the time of publication and are intended to assist in the safe use of the product.

The product may only be stored, handled and used in accordance with the instructions for use. It is the user's responsibility to take all necessary precautions when using the product.



The data sheet does not constitute any legal obligation or liability for the consequences of use under incorrect conditions or improper use, since the conditions of use (handling, application, storage, disposal, etc.) are beyond our control.

**Recommendation for training:** Persons working professionally with the product (qualified professional users) must be informed about the dangers of working with chemicals and about the general occupational safety and protection regulations within the framework of annual occupational safety training.

THE SAFETY DATA SHEET MUST BE AVAILABLE TO USERS.

**Classification of the mixture:** calculated based on the concentration and classification of the components.

**H-phrases and other abbreviations shown:** the numbers after the abbreviations in section 3 indicate the category within the class, higher numbers indicate lower hazard:

Acute Tox.: acute toxicity; oral: by mouth; dermal: through the skin; inhal.: by inhalation; Repr.: reproductive toxicity; STOT RE: specific target organ toxicity, repeated exposure; Skin Irrit: skin irritation; Eye Dam.: serious eye damage; Aquatic Acute: hazardous to the aquatic environment, acute hazard; Aquatic Chronic: hazardous to the aquatic environment, chronic hazard.

- H300 Fatal if swallowed.
- H302 Harmful if swallowed.
- H310 Fatal in contact with skin.
- H315 Causes skin irritation.
- H318 Causes serious eye damage.
- H330 Fatal if inhaled.
- H332 Harmful if inhaled.
- H360D May damage the unborn child.
- H372 Causes damage to organs (blood) through repeated or prolonged exposure.
- H373 May cause damage to organs (blood) through repeated or prolonged exposure.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.
- H412 Harmful to aquatic life with long lasting effects.

- ADR European Agreement Concerning the International Carriage of Dangerous Goods by Road
- ATE<sub>mix</sub> Acute Toxicity Estimate (mixture)
- BPC Biocidal Product Committee
- CAS Chemical Abstract Service numbers to help identify substances
- CLP Classification, Labelling and Packaging – Regulation (EC) No 1272/2008
- ECHA European Chemicals Agency - European Chemicals Agency
- EC-nr The number used to identify a substance in the European Union
- GHS Globally Harmonized System of Classification and Labelling of Chemicals
- IATA International Air Transport Association, International Air Transport Association, International
- ICAO International Civil Aviation Organization Dangerous Goods Regulations
- ICAO International Civil Aviation Organization Technical Instruction for the Safe Transport of Dangerous Goods by Air For Air Transport
- INR International Normalized Ratio – for standardizing the value of prothrombin activity expressed in %
- IMDG International Maritime Dangerous Goods Code
- K<sub>oc</sub> is the adsorption coefficient related to the organic carbon content
- M is the multiplier factor used to determine the acute and chronic aquatic environmental hazard using the weighted summation method
- OECD Organisation for Economic Co-operation and Development – Organisation for Economic Co-operation and Development
- PBT Persistent, Bioaccumulative, Toxic – persistent, bioaccumulative, toxic

Product name: **RATEX pellet bait**  
Version number: **6.0 - EN**  
Date: **2025. June 15**. Overwrites the previous version.



REACH Registration, Evaluation, Authorisation and Restriction of Chemicals – see Registration, Evaluation, Authorisation and Restriction of Chemicals. Regulation (EC) No 1907/2006  
RID Technical Instructions for the Safety of Dangerous Goods by Rail  
SVHC Substance of Very High Concern  
UFI Unique Formula Identifier  
vPvB very Persistent, very Bioaccumulative

The product is a distribution category III product, for general-, professional and trained professional use.

**When using biocides, pay attention to safety!**  
**Before each use, carefully read the label, the instructions for use, and the regulations for safe use!**  
**In order to avoid endangering human health and the environment, the regulations in the instructions for use must be followed!**

**The product safety data sheet is available and can be downloaded free of charge:**  
<http://www.metatox.com>

**Data sheet history:** This safety data sheet was prepared on 15 June 2025 based on the manufacturer's data and supersedes the previous version.  
The purpose of the amendment is to comply with Regulation (EU) 2020/878.