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Safety and efficacy of a feed additive consisting of Allura Red AC for small non-food-producing mammals and ornamental birds (Versele-Laga)

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Abstract

Following a request from the European Commission, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety and efficacy of Allura Red AC for small non-food-producing mammals and ornamental birds when used as an additive that add or restore colour in feedingstuffs. The use of Allura Red AC up to the proposed conditions of use of 500 mg/kg complete feed is considered safe for guinea pig, chinchilla, degu, hamster, gerbil and chipmunk. The following maximum safe levels (mg/kg complete feed) apply to the following species: ferrets 99, rabbits 123, canaries, budgerigars, mynah and toucans 45, lovebirds 51, cockatiels 79, cockatoos 115, amazons 145, parrots 147, yellow breast macaw 150, blue-throated macaw 173 and hyacinth macaw 214. The maximum safe level of Allura Red AC for other small non-food-producing mammal is 99 mg/kg feed and for other ornamental birds is 45 mg/kg feed. Inhalation exposure of Allura Red is regarded as hazardous. In the absence of data, the Panel cannot conclude on the potential of Allura Red to be a skin/eye irritant or a skin sensitiser. The FEEDAP Panel cannot conclude on the efficacy of the additive.

Keywords: Allura Red AC, colourant, small non-food-producing mammals and ornamental birds, safety, efficacy

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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from Versele-Laga[2] for authorisation of the product Allura Red AC when used as a feed additive for small non-food producing mammals and ornamental birds (sensory additives; functional group: colourants/substances that add or restore colour in feedingstuffs).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 4(1) (authorisation of a feed additive or new use of a feed additive). The particulars and documents in support of the application were considered valid by EFSA as of 3 June 2020.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the product Allura Red AC, when used under the proposed conditions of use (see Section 3.1.3).

1.2. Additional information

Allura Red AC is authorised as feed additive for cats and dogs.[3]

The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) adopted two opinions on the safety and efficacy of Allura Red (EFSA FEEDAP Panel, 2012a, 2015).

Allura Red AC, is also an approved food colourant in the EU, and it is listed in Annex II of Regulation (EC) No 1333/2008[4] for a limited number of foodstuffs with a maximum allowed usage level of 25–500 mg/kg food for various foodstuffs. Allura Red AC is also permitted in alcoholic beverages at levels up to 200 mg/L and in non-alcoholic beverages at levels up to 100 mg/L.

The EFSA Panel on Food Additives and Nutrient Sources Added to Food (ANS) issued a scientific opinion on the re-evaluation of Allura Red AC as a food additive in 2009 (EFSA ANS Panel, 2009) and a statement on Allura Red AC and other sulfonated mono azo dyes authorised as food and feed additives (EFSA ANS Panel, 2013). In 2015, EFSA ANS Panel issued an opinion on the refined assessment of Allura Red AC (EFSA ANS Panel, 2015).

Allura Red AC has previously been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1974 (JECFA, 1974), 1980 (JECFA, 1981), 1981 (JECFA, 1981) and 2017 (JECFA, 2017) and by the Scientific Committee for Food (SCF) in 1975 (European Commission, 1975), 1984 (European Commission, 1984) and 1989 (European Commission, 1989). Allura Red AC was evaluated in 2000 by the National Toxicological Program (NTP, 2000). In 2002, the Nordic Working Group on Food Toxicology and Risk Assessment (NNT, 2002) reviewed the current status and safety data on all food additives permitted in the EU, including Allura Red AC.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier[5] in support of the authorisation request for the use of Allura Red AC as a feed additive.

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2] Versele-Laga, Kapellestraat 70, 9800 Deinze, Belgium.
[3] COMMISSION IMPLEMENTING REGULATION (EU) 2020/197 of 13 February 2020 concerning the authorisation of Allura Red AC as a feed additive for cats and dogs. OJ L 42/4, 14.2.2020.
[4] REGULATION (EC) No 1333/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16.
[5] FEED dossier reference: FAD-2020-0013.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies, peer-reviewed scientific papers, other scientific reports to deliver the present output.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment and in the addendum to EURL evaluation report regarding the methods used for the control of the active substance in animal feed, are valid and applicable for the current application.[6]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Allura Red is in line with the principles laid down in Regulation (EC) No 429/2008[7] and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012b); Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEEDAP Panel, 2017a); Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b); Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018), Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019).

3. Assessment

Allura Red AC, a mono-azo colourant, is a sensory additive (functional group: colourants/substances that add or restore colour in feedingstuffs) intended to be used in feed of small non-food-producing mammals and ornamental birds without a maximum content.

3.1. Characterisation

The additive under application, Allura Red AC (synonymous CI Food Red 17, Food Red No. 40, FD&C Red No. 40), is identical to the active substance.

Allura Red AC is a synthetically produced mono-azo colourant, comprising primarily disodium 2-hydroxy-1-(2-methoxy-5-methyl-4-sulfonato-phenylazo) naphthalene-6-sulfonate ($C_{18}H_{14}N_2Na_2O_8S_2$; CAS (Chemical Abstracts Service) number 25956-17-6, EINECS (European List of Notified Chemical Substances) number: 247-368-0, molecular weight 496.42) and subsidiary colouring matters, together with sodium chloride and/or sodium sulfate as the principal uncoloured components. Although typically described as the disodium salt, the calcium and potassium salts are also permitted. The structural formula of Allura Red AC is given in Figure 1. Allura Red AC is a dark red powder or granules freely soluble in water (225 g/L at 25°C).[8]

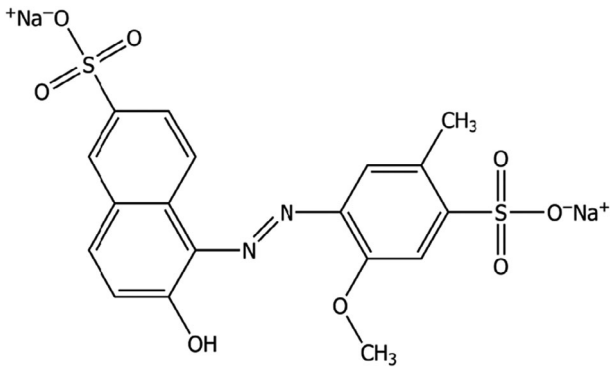

Figure 1: Structural formula of Allura Red

[6] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/default/files/amended-finrep-fad-2010-0347-allura-red.pdf.pdf

[7] Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

[8] Technical dossier/Supplementary information October 2021.

The specifications proposed for Allura Red AC when used as a feed additive are identical to those for Allura Red AC when used as a food additive laid down in Commission Regulation (EC) No 231/2012[9]. Thresholds are set for colouring matters (a minimum content of 85%, calculated as the sodium salt), water insoluble matter (≤ 2.0%), subsidiary colouring matter (≤ 3.0%), arsenic (≤ 3 mg/kg), lead (≤ 2 mg/kg), mercury (≤ 1 mg/kg), cadmium (≤ 1 mg/kg), organic compounds other than colouring matters (6-hydroxy-2-naphthalene sulfonic acid, sodium salt (≤ 0.3%); 4-amino-5-methoxy-2-methylbenezene sulfonic (≤ 0.2%) and 6,6-oxybis (2-naphthalene sulfonic acid) disodium salt (≤ 1.0%)), unsulfonated primary aromatic amines (calculated as aniline, ≤ 0.01%) and ether extractable matter (≤ 0.2%)).

Analysis of five production batches confirmed compliance with these specifications.[10]

The additive is produced in a number of different granulation sizes, depending on the intended use. Fine powders are used when the additive is added directly to feedingstuffs while a granular product is used for liquid application.

The dusting potential of three batches of the additive (fine powder) was determined using the Stauber-Heubach method and showed values on average of [redacted][11] The concentration of the active substance in the dust was not measured. The particle size distribution of the dust of the same three batches was analysed by laser diffraction method; the results (v/v) showed that on average, [redacted] The FEEDAP Panel notes that during dust generation, a fraction of small particles is present in the dust. However, as the solubility of the additive in water is 225 g/L, there is no need to further characterise the fraction of small particles potentially present in the additive (EFSA Scientific Committee, 2021).

3.1.1. Manufacturing process

Allura Red AC is formed when 4-amino-5-methoxy-2-methylbenezene sulfonic acid is diazotised with hydrochloric acid and sodium nitrite and coupled to 6-hydroxynaphthalene-2-sulfonic acid. Water is the only solvent used during manufacture of Allura Red AC.

3.1.2. Stability and homogeneity

No data were submitted. The applicant recommended a shelf-life of 36 months for Allura Red AC stored in a dry, cool and ventilated place, based on its own experience from the use of the product in food, cosmetics and other applications.

The applicant noted that the conditions of use for Allura Red AC in a range of foods are well established. Any substance that interacts with or alters conjugated unsaturated bonds of the molecule will affect the colour. Allura Red AC will generally be unstable in the presence of oxidising or reducing agents (e.g. sugars and acids).

No homogeneity data are required for colourings which add or restore colour to feed.

3.1.3. Conditions of use

Allura Red AC is intended to be used in feed for small non-food-producing mammals (including chinchilla, chipmunk, degu, ferret, gerbil, guinea pig, hamster, mouse, rabbit[12] and rat) and ornamental birds (including amazons, budgerigars, canaries, cockatiels, cockatoos, grey parrots, lovebirds, macaws (blue-throated; blue and yellow; hyacinth), mynah, toucans) without a maximum content. The applicant noted that the quantity required is dependent on the properties of the feedingstuffs, but in general is not likely to exceed 500 mg/kg complete feed.

The additive may be added to feed directly or via an intermediary step by dissolving it in water. The additive is not intended to be added to water for drinking.

[9] COMMISSION REGULATION (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. OJ L 83, p. 1, 22.3.2012.
[10] Technical dossier/Section II/ Annex_II_1.
[11] Technical dossier/Supplementary information November 2020/Report #20.
[12] The FEEDAP Panel noted that according to Regulation EC (No) 429/2008 rabbits are considered food-producing animals.

3.2. Safety

For the current evaluation, the applicant made reference to a number of EFSA opinions (EFSA, 2009; EFSA ANS Panel, 2013; EFSA FEEDAP Panel, 2012, 2015) and evaluations of other assessment bodies such as the Scientific Committee on Food (SCF) in 1975, 1984 and 1989 (European Commission, 1975, 1984, 1989), the Nordic Working Group on Food Toxicology and Risk Assessment (NNT, 2002), the National Toxicological Program (NTP, 2000), the Scientific Committee on Cosmetic Products and Non-food Products Intended for consumer concerning Curry Red (synonymous of Allura Red) (SCCNFP, 2004) and the World Health Organisation (WHO) Joint Expert Committee on Food Additives (JECFA) in 1974, 1980, 1981 and 2017 (JECFA, 1974, 1980, 1981, 2017).

The applicant also performed a literature search covering 20 years, up to October 2018, to complement the previous assessments with regard to the target animal safety and human safety (including user safety). The literature search was performed according to the principles set in the FEEDAP guidance on the renewal of feed additives (EFSA FEEDAP Panel, 2013). The following databases were consulted: AdisInsight: Trials, AGRICOLA, AGRIS, Allied & Complementary Medicine™, Aqualine, Aquatic Science & Fisheries Abstracts (ASFA), Aquatic Science & Fisheries Abstracts (ASFA), BIOSIS® Toxicology, BIOSIS Previews®, CAB ABSTRACTS, Embase®, Environment Abstracts, Foodline®: SCIENCE, FSTA®, MEDLINE®, NTIS: National Technical Information Service, Risk Abstracts, ToxFile®, Toxicology Abstracts, Toxicology Abstracts, Zoological Record Plus. Details on the search strategy were given in the dossier. A total of 21 articles were selected (total of papers found 524) and evaluated at the abstract stage and 13 abstracts were selected for a review of the full text. Three articles were included and summarised in the technical dossier while the remaining 10 articles were excluded on the basis that they did not investigate Allura Red AC on its own (i.e. the colour additive was commonly mixed with other colours), evaluated endpoints not relevant to safety, were narrative review articles that did not include new information, or concerned analytical methodology.

The FEEDAP Panel assessed the outcome of the literature review and the relevant papers are described in the assessment below.

3.2.1. Toxicology of Allura Red

3.2.1.1. Genotoxicity

The genotoxicity of Allura Red AC was already assessed by EFSA in 2009 (EFSA, 2009), 2012 (EFSA FEEDAP Panel, 2012a), 2013 (EFSA ANS Panel, 2013) and in 2015 (EFSA FEEDAP Panel, 2015).

In 2012, the FEEDAP Panel concluded that, although Allura Red AC was negative in bacterial reverse mutation assay, it was positive in two *in vivo* comet assays in mice (stomach and colon), and it was not possible to exclude a genotoxic potential of Allura Red AC (EFSA FEEDAP Panel, 2012). The FEEDAP opinion was updated in 2015 following the submission of a negative *in vivo* comet assay in mice (later published by Bastaki et al., 2017) and it was concluded that Allura Red AC is not genotoxic (EFSA FEEDAP Panel, 2015).

For the current assessment, the applicant submitted *in vitro* and *in vivo* studies already evaluated in EFSA previous opinions (EFSA FEEDAP Panel, 2012a, 2015) and relevant published studies which are assessed below.

An *in vivo* micronucleus test was performed in peripheral blood cells from male FVB mice to evaluate the potential of Allura Red AC to induce chromosomal damage (Abramsson-Zetterberg and Ilbäck, 2013).[13] Animals were treated by a single intraperitoneal injection (i.p.) of Allura Red AC at 100, 200, 400, 600, 800, 1,000, 1,500 and 2,000 mg/kg body weight (bw). The authors considered advantageous i.p. administration for a test item with low uptake from the intestines. Uptake and systemic exposure to Allura Red AC were confirmed in subgroups of mice exposed to 200 and 600 mg/kg bw, in which tissue samples (liver, kidneys, brain) were dissected for visual examination of changes in tissue colour. Forty-six hours after dosing, blood samples were collected from the orbital plexus and processed for the analysis of micronuclei by flow cytometry. At least 35,000 polychromatic erythrocytes (PCEs) were scored for each animal for the analysis of micronuclei. The positive control chemical induced a statistically significant increase of the micronucleus frequency, confirming the sensitivity of the assay. No cytotoxicity was induced by treatment with the test item, as measured by the frequencies of PCE (%PCE). Comparable frequencies of micronucleated polychromatic erythrocytes (fMNPCE) were observed between treated and control groups.

[13] Technical dossier/Section III/Reference III_1.

An *in vivo* micronucleus test was conducted in accordance with OECD TG 474 (1997) in bone marrow cells from CD1 mice orally administered for 2 days with Allura Red AC at 500, 1,000 and 2,000 mg/kg bw (Honma, 2015). Mice were killed 24 h after the final treatment. Two thousand polychromatic erythrocytes (PCEs) per animal were analysed to assess the frequency of micronuclei. No clinical signs of toxicity were induced by treatment with the test item. The positive control chemical induced a statistically significant increase of the micronucleus frequency, confirming the sensitivity of the assay. No cytotoxicity was induced by treatment with the test item, as measured by the frequency of PCE (%PCE). Comparable frequencies of micronucleated polychromatic erythrocytes were observed between treated and control groups.

An *in vivo* comet assay was performed in male CD2F1 mice to investigate the potential of Allura Red AC (Food Red No. 40) (87.5% purity) to induce DNA damage in liver and glandular stomach (Honma, 2015).[14] The study was conducted in accordance with OECD TG 489 (2014). Mice were treated by gavage once per day on two consecutive days at 500, 1,000 and 2,000 mg/kg bw and sacrificed 3 h after last administration. No clinical signs of toxicity were observed. One hundred cells per animal were analysed to measure percentage of tail DNA, Olive tail moment and tail length as indicators of DNA damage. Numbers of heavily damaged cells (hedgehogs) were also determined. No significant differences were observed in DNA damage parameters between treated and control groups, while the positive controls performed as expected.

A transgenic rodent (TGR) gene mutation assay was conducted in liver and glandular stomach to evaluate the potential induction of gene mutations by Allura Red AC in the cII gene using Muta^{TM} Mice (Honma, 2015).[14] The experiment was performed in accordance with OECD TG 488 (2013). The test substance was orally administered daily for 4 weeks at 250, 500 and 1,000 mg/kg bw; the highest dose (1,000 mg/ kg bw) was the top recommended dose by OECD TG 488. Mice were killed 3 days after the final treatment. No clinical signs of toxicity were observed. Mutant frequencies (MF) in treated animals were not significantly different from values measured in the negative control group. The positive control significantly increased MFs in the liver ($p < 0.05$);the increase of MFs observed in the stomach did not attain the statistical significance, but was considered adequate as positive control in TGR assay.

The FEEDAP Panel concludes that the new studies showed that Allura Red AC is not genotoxic and supports the previous conclusions from the FEEDAP Panel (EFSA FEEDAP Panel, 2015).

3.2.1.2. General toxicology

The toxicity of Allura Red AC was evaluated in the past years by EFSA (EFSA 2009; EFSA ANS Panel, 2013; EFSA FEEDAP Panel, 2012a, 2015) and other assessment bodies (JECFA, 1974, 1980, 1981, 2017; European commission, 1975, 1984, 1989; NTP, 2000; NNT, 2002).

For the current assessment, the applicant submitted the original reports of the studies already assessed in the evaluations mentioned above. Although some of these studies were performed according to standards appropriate to the time, but in some cases, they were not in accordance either with good laboratory practice (GLP) or with previous and current OECD guidelines, the FEEDAP Panel considered the amount and quality of the studies sufficient for the assessment.

Overall, the FEEDAP Panel agrees with the assessment performed by the above-mentioned assessment bodies and an overview of the main results is given below.

Previous evaluations reported short-term and subchronic toxicity studies with Allura Red AC in rats, dogs and pigs revealing no compound-related effects other than colouration of the urine and faeces.[15]

The chronic toxicity and carcinogenicity of Allura Red AC were assessed in previous evaluations in two studies in mice[16] and two studies in rats.[17] The no observed adverse effect level (NOAEL) from the mice studies was 5.19%, the highest dose tested, equivalent to 7,318 and 8,356 mg/kg bw per day in males and females, respectively. In the first study in rats, the lowest NOAEL was 1.39%, equivalent to 695 mg/kg bw per day, based on reduced body weight in both sexes. The lowest NOAEL from the second study in rats was 695 mg/kg bw per day for females for reduction of body weight (later defined to be equivalent to 901 mg/kg bw per day by Borzelleca et al., 1989). A dog study[18] in which Allura Red AC was administered for 104 weeks was considered not adequate to derive an NOAEL due to the limited information available (EFSA, 2009).

[14] Technical dossier/Section III/Reference III_32.
[15] Technical dossier/Section III/References 65, 74, 75.
[16] Technical dossier/Section III/References 8, 57, 63.
[17] Technical dossier/Section III/References 7, 50, 62.
[18] Technical dossier/Section III/Reference 51.

Several reproductive and developmental toxicity studies on Allura Red AC have been conducted in mice, rats and rabbits. A reproductive toxicity study in rats gave an NOAEL of 1.39% feed (13,900 mg/kg feed, equivalent to 695 mg/kg bw per day), based on growth suppression in pups.[19] An lowest observed adverse effect level (LOAEL) of 2.5% (equivalent 1,250 mg/kg bw per day) was established in a two-generation reproductive study in rats in which there was no clear dose-response relation for the reported effects in this study.[20] In another two-generation reproductive study, no treatment-related reproductive or developmental effects were observed. Few effects on either movement activity or maze learning in both sexes of the F1 generation were reported; however, these effects were not considered adverse.[21] The aforementioned long-term studies in rats and mice included reproductive and developmental toxicity investigations. No treatment-related effects on reproduction and development were reported. Four teratogenicity studies were reported in rats administered Allura Red AC by gavage or via drinking water.[22] No maternal or developmental treatment-related effects were observed, except in one study[23] in which a significant increase in the incidence of fetuses with reduced ossification of the hyoid was observed at 939 mg/kg bw per day; the identified NOAEL for this study was 546 mg/kg bw per day.

An NOAEL of 700 mg/kg bw per day was identified in a teratogenicity study in rabbits[24] in which no treatment-related effects on appearance, behaviour, body weight, gross necropsy findings, implantation, litter data or other foetal abnormalities were observed.

3.2.1.3. Conclusions on toxicology

Allura Red AC is not genotoxic. The FEEDAP Panel concludes that toxicological studies in laboratory animals showed no alerts for particular adverse effects that need to be taken into consideration when assessing target species safety. Allura Red AC was not carcinogenic and did not cause reproduction/ developmental toxicity. The relevant NOAEL for the calculation of the safe level in feed of the target animals was 695 mg Allura Red AC/kg body weight per day (derived from studies in rats for growth suppression in pups in a reproduction study and reduced body weight in rat long-term studies).

3.2.2. Safety for the target species

The additive is intended to be used in small non-food-producing mammals (including chinchilla, chipmunk, degu, ferret, gerbil, guinea pig, hamster, mouse, rabbit and rat) and ornamental birds (including amazons, budgerigars, canaries, cockatiels, cockatoos, grey parrots, lovebirds, macaws (blue-throated; blue and yellow; hyacinth), mynah, toucans).

A number of subchronic and chronic feeding studies with Allura Red AC in mice and rats for duration of over 1 year have been previously mentioned in chapter 3.2.1.2. From these studies, no adverse effects were seen in rats and mice at concentrations in the diet of up to 1.39% (13,900 mg/kg feed) and 5.19% (51,900 mg/kg feed), respectively. The lowest NOAEL was 13,900 mg Allura Red AC/kg feed, rounded to 14,000 mg /kg feed, which can be used for the assessment of the target animal safety. The maximum safe level in rats and mice can be calculated considering the lowest NOAEL of 14,000 mg/kg feed and an uncertainty factor (UF) of 10 for intraspecies variability, which would result in a maximum safe level of 1,400 mg/kg feed.

No tolerance studies were submitted for the remaining species object of this application; therefore, the safe levels in feed for these species were calculated following the procedure described in the Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b).

For the rest of the species, the maximum safe level can be calculated using the NOAEL, considering the feed intake and body weight of the different species and applying an uncertainty factor. The applicant submitted comprehensive data[25] on body weight and feed intake of the animal species under application, except for mynah and toucans. The feed intake per kg bw for the different species was calculated using default values provided by the applicant derived from feed intake expressed in relation to body weight. The feed intake per kg bw was calculated using the lowest feed intake in relation to the lowest body weight and with the highest feed intake to the highest body weight. From this

[19] Technical dossier/Section III/Reference 6.
[20] Technical dossier/Section III/Reference 69.
[21] Technical dossier/Section III/Reference 66.
[22] Technical dossier/Section III/ References 12, 13, 14, 15.
[23] Technical dossier/Section III/ References 14.
[24] Technical dossier/Section III/ References 56.
[25] Britsch (2000), BSAVA (2002), ExoticDirect (2017), Kamphues et al., 1999, PDSA (2021), PFMA (2021), Wolf and Kamphues (2004a), Woods and Boracker (1975).

calculation, the highest quotient was chosen as default value. The data provided for chipmunk, canaries and budgerigars were not deemed to be reliable (i.e. resulting in a very high feed intake per kg bw) and therefore were not considered for the assessment. For rabbits, the FEEDAP Panel retained the data available in the FEEDAP Guidance on the assessment of the safety for the target species (EFSA FEEDAP Panel, 2017b).

For the uncertainty factor, the Panel considers that the physiological proximity of most exotic mammals listed in the application (chinchilla, chipmunk, degu, gerbil, guinea pig, hamster) to the laboratory rodents allows to use a UF of 10, while for rabbits, ferrets and ornamental birds, an UF of 100 should be used.

The calculated maximum safe dietary levels of Allura Red AC for the different species are reported in Table 1.

Table 1: Calculated maximum safe dietary levels of Allura Red AC for small non-food-producing mammals and ornamental birds

Species	Feed intake (g DM/kg bw)	Maximum safe dietary level (mg/kg feed)
Non-food-producing mammals		
Rabbit	50	123
Guinea pig	44	1,390
Chinchilla	73	834
Degu	52	1,178
Hamster (Syrian Golden)	59	1,043
Gerbil	62	979
Ferret	62	99
Ornamental birds		
Lovebirds	120	51
Cockatiels	77	79
Cockatoos	53	115
Grey parrots	42	147
Amazons	42	145
Macaws		
Blue-throated	35	173
Yellow breast	41	150
Hyacinth	29	214
Canaries, budgerigars, mynah, toucans	136(1)	45(1)

(1): EFSA FEEDAP Panel (2016).

Based on the results obtained, the FEEDAP concludes that the use of the additive at levels not exceeding 500 mg/kg feed would be safe for guinea pig, chinchilla, degu, hamster and gerbil as well as chipmunk, the latter being not essentially different from the other rodents for which the data were considered reliable. For rabbits and ferrets, the safe levels are 123 and 99 mg/kg complete feed, respectively. The lowest level of 99 mg/kg is considered to apply to other small non-food-producing mammal species.

Based on the data provided by the applicant on feed intake and body weight, the maximum safe dietary levels for ornamental birds was calculated and it ranged from 51 to 214 mg/kg feed. The data for some ornamental bird species object of this application was not reliable (canaries and budgerigars) or not available (mynah and toucans). The maximum safe dietary level for these species was calculated considering the conservative values for body weight and feed intake of ornamental birds already used by the FEEDAP Panel in a previous opinion (EFSA FEEDAP Panel, 2016). These values would result in a maximum safe dietary level of 45 mg Allura Red AC/kg feed for canaries, budgerigars, mynah and toucans and will apply to other ornamental bird species.

3.2.2.1. Conclusions on safety for the target species

The use of Allura Red AC up to proposed conditions of use of 500 mg/kg complete feed is considered safe for guinea pig, chinchilla, degu, hamster, gerbil and chipmunk. For rabbits and ferret

the safe use levels are 123 and 99 mg/kg, respectively. For other small non-food-producing mammal species, the safe level is 99 mg/kg feed.

The safe level for canaries, budgerigars, mynah and toucans is 45 mg/kg complete feed, for lovebirds 51 mg/kg feed, cockatiels 79 mg/kg feed, cockatoos 115 mg/kg feed, amazons 145 mg/kg feed, parrots 147 mg/kg feed, yellow breast macaw 150 mg/kg feed, blue-throated macaw 173 mg/kg feed and hyacinth macaw 214 mg/kg feed. For other ornamental birds, the safe level is 45 mg/kg.

3.2.3. Safety for user

3.2.3.1. Effects on the respiratory system

Allura Red AC has a high dusting potential (range 9.7–10.9 g/m^3) and particle size measurement of the dust showed the presence of a fraction of small particles (see Section 3.1); therefore, users are considered as being at risk of inhalation exposure to dust from the additive. In the absence of information on the inhalation toxicity of Allura Red AC, such exposure is regarded as hazardous.

3.2.3.2. Effects on eyes and skin

For the evaluation of the effects on eyes and skin, the applicant submitted a published paper (Fulton, 1989) and mentioned the results of studies described in reports from other assessment bodies, in particular the JECFA safety evaluation of certain food additives, including Allura Red AC (JECFA, 2017) and the opinion of the Scientific Committee on Cosmetic Products and Non-food Products Intended for consumer concerning Curry Red (synonymous of Allura Red AC) (SCCNFP, 2004). The FEEDAP Panel noted that the original reports of the studies mentioned by the applicant were not submitted for the current assessment.

A summary of the main results described in JECFA and SCCNFP reports is given below.

In JECFA report, three studies investigating the skin irritation/sensitisation of Allura Red AC in humans volunteers are described (Osbourn, 1972 – as quoted in JECFA, 2017, Jolly, 1973 – as quoted in JECFA, 2017). According to JECFA's assessment, Allura Red AC is not a skin irritant or sensitiser.

In the SCCNFP report (SCCNFP, 2004), the evaluation of the skin irritation potential of Allura Red AC was based on the assessment of a study also submitted in the dossier (Fulton, 1989we) and on additional information from two studies in rabbits and a patch test in human. According to the SCCNFP report, the study by Fulton (1989), not performed according to OECD Guideline 404, showed that Allura Red AC produced a slight skin irritation in rabbits under the experimental condition described (the noted grade of irritation after the repeated open application was 2 (maximum score 5)). Although the SCCNFP noted that the experimental findings are available as short summaries lacking key information (e.g. concentration tested, concentrations causing effects after repeated applications) or were obtained under non-standard test conditions, in the report it is concluded that 'the available information suggests, that Curry Red [Allura Red AC] is not likely to cause skin irritation, especially at the intended maximum concentration in hair dye formulations of 0.4%'.

Based on the assessment of a study performed in mice according to OECD 429, and a human patch test study on human volunteers, the SCCNFP concluded that Allura Red AC is not a skin sensitiser.

Limited information on the eye irritation potential of Allura Red AC is given in the SCCNFP evaluation in which it is reported that Allura Red AC revealed no eye-irritating properties in rats when applied to eyes in a 0.1% and 1% dilution in water (no details given). In addition, based on the results of *in vitro* assays (Hen's egg test on the chorioallantoic membrane (HET-CAM) and a test for the assessment of the eye irritation potential by cytotoxicity measurement in the neutral red uptake assay (NRU) on human keratinocytes (HaCat)), the SCCNFP concluded that Curry Red [Allura Red AC] was considered non-irritant. However, it was noted that these assays were not validated and have limitations for use with coloured substances.

The FEEDAP Panel evaluated the published paper of Fulton (1989) and the summaries of the other studies assessed in the JECFA and SCCNFP reports on the skin irritancy/sensitisation and eye irritancy of Allura Red AC. In the absence of the full reports of the studies evaluated by JECFA and SCCNFP, the FEEDAP Panel cannot conclude on the potential for Allura Red AC to be an eye or skin irritant or a skin sensitiser.

3.2.3.3. Conclusions on safety for the user

In the absence of information on the inhalation toxicity of Allura Red AC, such exposure is regarded as hazardous. In the absence of data, the Panel cannot conclude on the potential of Allura Red to be a skin/eye irritant or a skin sensitiser.

3.2.4. Safety for the environment

The additive Allura Red AC is intended to be used in non-food-producing animals.[26] No environmental risk assessment is necessary for such use.

3.3. Efficacy

Allura Red AC is intended to be used to colour the food for small non-food-producing mammals and ornamental birds. Where the function requested for feed is the same as that used in food, no further demonstration of efficacy might be necessary (Regulation (EC) No 429/2008).[18]

However, considering the wide variety of feedingstuffs used in complete and complementary feed for small non-food-producing mammals and ornamental birds and the uncertainty of which concentration of Allura Red AC would result in a visible effect, an effect demonstration is required (EFSA FEEDAP Panel, 2018).

The applicant provided pictures of two feed samples (one not containing Allura Red AC and another one containing it) which provided visual demonstration of the efficacy of Allura Red AC to colour feed.[27] The applicant provided also spectroscopy data showing that the amount of Allura Red AC required to reproduce the colouration of the coloured sample in the uncoloured sample was 190 mg Allura Red AC/kg feed.

The FEEDAP Panel noted that no indication is given on the type of animal feed for which the visual demonstration and spectroscopy data are provided and that two more studies are needed to cover a representative range of feed to which the additive will be applied in line with the requirements of the FEEDAP Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018).

The FEEDAP Panel cannot conclude on the efficacy of Allura Red AC when used in feed for small non-food-producing mammals and ornamental birds.

4. Conclusions

The use of Allura Red AC up to the proposed conditions of use of 500 mg/kg complete feed is considered safe for guinea pig, chinchilla, degu, hamster, gerbil and chipmunk. The following maximum safe levels (mg/kg complete feed) apply to the following species: ferrets 99, rabbits 123, canaries, budgerigars, mynah and toucans 45, lovebirds 51, cockatiels 79, cockatoos 115, amazons 145, parrots 147, yellow breast macaw 150, blue-throated macaw 173 and hyacinth macaw 214.

The maximum safe level of Allura Red AC for other small non-food-producing mammal is 99 mg/kg feed and for other ornamental birds is 45 mg/kg feed.

Inhalation exposure of Allura Red is regarded as hazardous. In the absence of data, the Panel cannot conclude on the potential of Allura Red to be a skin/eye irritant or a skin sensitiser.

The FEEDAP Panel cannot conclude on the efficacy of the additive.

5. Documentation as provided to EFSA/Chronology

Date	Event
11/02/2020	Dossier received by EFSA. Allura Red as sensory additive. Submitted by Versele-Laga.
16/03/2020	Reception mandate from the European Commission
03/06/2020	Application validated by EFSA – Start of the scientific assessment
15/07/2020	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation of the additive*
23/11/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
25/02/2021	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: user safety*
25/05/2021	Reception of supplementary information from the applicant - Scientific assessment re-started
5/10/2021	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: safety for the target species*
15/10/2021	Reception of supplementary information from the applicant - Scientific assessment re-started

[26] The Panel notes that even if rabbits are included in the application, the request is for use in non-food-producing animals, and therefore, no environmental risk assessment is considered necessary for this application.
[27] Technical dossier/Section IV/Annex_IV_1.

Date	Event
22/10/2021	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation of the additive*
26/10/2021	Reception of supplementary information from the applicant - Scientific assessment re-started
20/02/2020	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
11/11/2021	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

ANS	EFSA Scientific Panel on Additives and Nutrient Sources added to Food
BW	body weight
CAS	Chemical Abstracts Service
DM	dry matter
EURL	European Union Reference Laboratory
FAO	Food Agricultural Organization
GLP	good laboratory practice
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
LOAEL	low observed adverse effect level
NOAEL	no observed adverse effect level
NNT	Nordic Working Group on Food Toxicology and Risk Assessment
NTP	National Toxicology Program
OCAC	United States Office of Cosmetics and Colours
SCF	Scientific Committee on Food
SCCNFP	Scientific Committee on Cosmetic Products and Non-food Products Intended for consumer
UF	uncertainty factor
WHO	World Health Organization