

——结合 [GB2760-2014《食品安全国家标准 食品添加剂使用标准》](#)（点击查看-P58）12.01 盐及代盐制品使用抗结剂新增酒石酸铁的情况，特介绍 [欧盟第2015/1739号条例](#) 供企业在必要时贯标参考（壹佰 20240123）

欧州联盟官方公报 第 253/3 页 2015. 9. 30 中文

欧盟第 2015/1739 号委员会条例

2015 年 9 月 28 日

修订欧洲议会和理事会第 1333/2008 号条例（EC）附件二和第 231/2012 号委员会条例（EU）附件，涉及酒石酸铁作为盐及代盐制品中的抗结剂的使用（与欧洲经济区相关的文本）

欧盟委员会，考虑到《欧洲联盟运作条约》，考虑到欧洲议会和理事会 2008 年 12 月 16 日关于食品添加剂的第 1333/2008 号条例（EC）[\(1\)](#)，特别是其中第 10（3）条和第 14 条，考虑到欧洲议会和理事会 2008 年 12 月 16 日第 1331/2008 号条例（EC），该条例规定了食品添加剂、食品酶和食品香料的共同授权程序 [\(2\)](#)，特别是其中的第 7（5）条，鉴于：

1. 第 1333/2008 号法规（EC）附件二列出了欧盟批准用于食品的食品添加剂及其使用条件。

2. 欧盟委员会第 231/2012 号条例 [\(3\)](#) 规定了第 1333/2008 号条例（EC）附件二和附件三所列食品添加剂的规格。

3. 该清单可根据第 1331/2008 号（EC）条例第 3 条第（1）款所

述的共同程序进行更新，可由委员会主动或在申请后进行。

4. 2012年1月18日，提交了一份申请，要求授权在盐及代盐制品中使用酒石酸铁作为抗结剂。该申请已根据第1331/2008号（EC）条例第4条提供给成员国。

5. 欧洲食品安全局评估了酒石酸铁作为食品添加剂的安全性，酒石酸铁是酒石酸钠和三氯化铁的络合产物，在其2014年12月9日的意见（4）中得出结论，考虑到毒理学数据和暴露评估中包含的保守假设，在建议的使用水平上将其用作盐及代盐制品的抗结块剂没有安全问题。

6. 在盐及代盐制品中添加抗结剂被认为是必要的，以改善流动性，并避免在暴露于湿气和储存过程中形成硬化的团聚体。酒石酸铁的使用可以作为其他目前授权添加剂的替代品，如亚铁氰化物（E 535-538）和二氧化硅、硅酸盐（E 551-553）。因此，适当授权在盐及代盐制品中使用酒石酸铁作为抗结剂，并将E 534作为该添加剂的E编号是合适的。

7. 当酒石酸铁（E 534）首次被列入第1333/2008号法规（EC）附件二中规定的欧盟食品添加剂清单时，其规格应纳入第231/2012号法规（EU）。

8. 因此，（EC）第1333/2008号和（EU）第231/2012号条例应相应修订。

（9）本条例规定的措施符合植物、动物、食品和饲料常务委员会的意见，

已采纳本规定：

第 1 条 根据本法规附件一，对第 1333/2008 号法规（EC）附件二进行了修订。

第 2 条 根据本法规附件二，对第 231/2012 号法规（EU）附件进行了修订。

第 3 条 本条例自其在《欧盟官方公报》上公布之日起第二十天生效。

本条例应具有整体约束力，并直接适用于所有成员国。

2015 年 9 月 28 日于布鲁塞尔

委员会主席 让-克劳德·容克

(1) OJ L 3542008 年 12 月 31 日，第 16 页。

(2) OJ L 3542008 年 12 月 31 日，第 1 页。

(3) 2012 年 3 月 9 日第 231/2012 号委员会条例（EU）规定了欧洲议会和理事会第 1333/2008 号条例（EC）附件二和附件三所列食品添加剂的规格（OJ L 832012 年 3 月 22 日，第 1 页）。

(4) 欧洲食品安全局杂志 2015；13(1):3980

附件一

欧洲共同体第 1333/2008 号条例附件一修订如下：

EC 编号	名称	食品	最大使用量	备注
E530				
E534	酒石酸铁	盐及代盐制品	110mg/kg	(92): 以干物质计
E338-452				
E534	酒石酸铁	盐及代盐制品	110mg/kg	(92): 以干物质计

附件二

在第 231/2012 号法规的附件 (EU) 中，在食品添加剂 E 530 的条目后，将插入以下新条目：

E534 酒石酸铁	
同义词	酒石酸铁，酒石酸钠与氯化铁 (III) 的络合产物
定义	酒石酸铁是通过将 L-酒石酸盐异构化为 D-、L-和内消旋酒石酸盐的平衡混合物，然后加入三氯化铁来制备的
CAS 号	1280193-05-9
化学名称	D(+)-、L(-)- 和内消旋 2,3 二羟基丁二酸的铁 (III) 络合产物
化学公式	$\text{Fe}(\text{OH})_2\text{C}_4\text{H}_4\text{O}_6\text{Na}$
分子量	261,93
检测	
内消旋酒石酸盐	> 28%，以干基阴离子表示
D(-)- 和 L(+)-酒石酸盐	>10%，以干基阴离子表示
铁 (III)	>8%，以干基阴离子表示
描述	深绿色的水溶液，通常包含约 35 量%重的络合产物
识别	极易溶于水
	酒石酸盐和铁检测呈阳性
	35%络合产物水溶液的 pH 值在 3.5 至 3.9 之间
纯度	
氯化物	不超过 25%
钠	不超过 23%
砷	不超过 3mg/kg
铅	不超过 2mg/kg
汞	不超过 1mg/kg
草酸盐	以干基草酸盐表示，不超过 1.5%

Regulation-2015/1739-EN-EUR-Lex
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.253.01.0003.01.ENG

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COMMISSION REGULATION (EU) 2015/1739 of 28 September 2015

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of the iron tartrate as an anti-caking agent in salt and its substitutes

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,
Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (1), and in particular Articles 10(3) and 14 thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (2), and in particular Article 7(5) thereof,

Whereas:

(1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food and their conditions of use.

(2) Commission Regulation (EU) No 231/2012 (3) lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.

(3) That list may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application.

(4) On 18 January 2012, an application was submitted for the authorisation of the use of iron tartrate as an anti-caking agent in salt and its substitutes. The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.

(5) The European Food Safety Authority evaluated the safety of iron

tartrate, which is a complexation product of sodium tartrate and iron (III) chloride, as a food additive and in its opinion (4) of 9 December 2014 concluded that, taking into account toxicological data and the conservative assumptions included in the exposure assessment, there is no safety concern for its use as an anti-caking agent in salt and its substitutes at the level of use proposed.

(6) Addition of an anti-caking agent to salt and its substitutes is considered necessary in order to improve flow properties and to avoid the formation of hardened agglomerates when exposed to moisture and during storage. The use of iron tartrate can serve as an alternative to other currently authorised additives, such as ferrocyanides (E 535–538) and silicon dioxide silicates (E 551–553). It is therefore appropriate to authorise the use of iron tartrate as an anti-caking agent in salt and its substitutes and to assign E 534 as E-number to that additive.

(7) The specifications for iron tartrate (E 534) should be included in Regulation (EU) No 231/2012 when it is included in the Union list of food additives laid down in Annex II to Regulation (EC) No 1333/2008 for the first time.

(8) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with Annex I to this Regulation.

Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 28 September 2015.

For the Commission The President

Jean-Claude JUNCKER

(1) OJ L 354, 31.12.2008, p. 16.

(2) OJ L 354, 31.12.2008, p. 1.

(3) 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, 22. 3. 2012, p. 1).

(4) EFSA Journal 2015; 13(1): 3980

ANNEX I

Annex II to Regulation (EC) No 1333/2008 is amended as follows:

(1) In Part B, point 3 'Additives other than colours and sweeteners', the following new entry is inserted after the entry for food additive E 530:

E 534	Iron tartrate
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(2) In Part E is amended as follows:

(a) in category 12.1.1 'Salt':

(i) the following new entry is inserted after the entry for food additive E 530:

E 534	Iron tartrate	110	(92)
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(ii) the following footnote is added:

	(92): Expressed on dry matter
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(b) in category 12.1.2 'Salt substitutes':

(i) the following new entry is inserted after the entry for food additive E 338-452:

E 534	Iron tartrate	110	(92)
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(ii) the following footnote is added:

	(92): Expressed on dry matter
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ANNEX II

In the Annex to Regulation (EU) No 231/2012, the following new entry is inserted after the entry for food additive E 530:

'E 534 IRON TARTRATE	
Synonyms	Iron meso-tartrate, complexation product of sodium tartrate with iron(III) chloride
Definition	Iron tartrate is manufactured by the isomerisation of L-tartrate to an equilibrium mixture of D-, L- and meso-tartrate followed by addition of iron(III) chloride.
CAS number	1280193-05-9
Chemical name	Iron(III) complexation product of D(+)-, L(-)- and meso-2,3 dihydroxybutanedioic acids
Chemical formula	Fe(OH) ₂ C ₄ H ₄ O ₆ Na
Molecular weight	261,93
Assay	
meso-tartrate	> 28 %, expressed as the anion on dry basis
D(-)- and L(+)-tartrate	> 10 %, expressed as the anion on dry basis
Iron(III)	> 8 %, expressed as the anion on dry basis
Description	Dark green aqueous solution typically comprising ca 35 % by weight complexation products
Identification	Highly soluble in water
	Positive tests for tartrate and iron
	pH of a 35 % aqueous solution of complexation products between 3,5 and 3,9
Purity	
Chloride	Not more than 25 %
Sodium	Not more than 23 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg
Oxalate	Not more than 1,5 % expressed as oxalate on dry basis