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# Specialty Food & Pharma Ingredients you can trust

## Quality Information Pack

Sunett®
Brand Sweetener

**(Acesulfame K)**

## Version March 2020

Released by:


Giacomo Vitarelli
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Food Ingredients


### Disclaimer

The information presented in this Sunett® Quality Information Pack is based on our present state of knowledge and is intended to provide general notes on our products and their uses. It must not be construed as guaranteeing specific properties of the products described herein or their suitability for a particular application. The user of Sunett® is solely responsible for investigating whether existing patents are infringed by the use of Sunett®. Additionally, the user is solely responsible for investigating and checking the regulatory approval status with respect to any intended use of Sunett®. Any sales and/or the deliveries of Sunett® are always subject to our General Terms and Conditions, unless otherwise agreed between the parties in writing. Any reference to laws, regulations, standards, guidelines etc. refers to such laws, regulations, standards, guidelines etc. as in force and effect as at March 2020.

COMMITTED
Celanese
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TO QUALITY

## Table of Contents

## 1. CONTACTS

| | |
|---|---|
| Address: | Celanese Sales Germany GmbH<br>Am Unisys-Park 1<br>65843 Sulzbach (Taunus)<br>Germany |
| Manufacture by: | Celanese Production Germany GmbH & Co. KG<br>Am Unisys-Park 1<br>65843 Sulzbach (Taunus)<br>Germany |
| Production Facility: | Sunett® Plant, Building D 483<br>Industriepark Höchst<br>65926 Frankfurt / Main<br>Germany |
| Quality Contact: | Mr. Frank Goergen<br>Sr. Manager Quality & Food Safety<br>Phone: +49 (0)69 45009 1378<br>Fax: +49 (0)69 45009 58294<br>E-mail: frank.goergen@celanese.com |
| Product Stewardship/<br>Regulatory Contact: | Dr. Mari Stavanja<br>Sr. Principal Product Stewardship<br>Phone: +1 972 443 4983<br>E-mail: mari.stavanja@celanese.com |
| Contact for Sales/<br>General Inquiries | |
| EMEA: | Phone: +49 (0)69 45009 1663<br>E-mail: foodingredients-emea@celanese.com |
| Asia: | Phone: +81-3-6280-5327<br>E-mail: foodingredients-AP@celanese.com |
| Americas: | Phone: +1-800-786-3883<br>E-mail: foodingredients-AM@celanese.com |
| Web: | www.celanese.com/food-ingredients/about-us.aspx |
| **Emergency Contact:** | 24 h Emergency No: +49 (0)69 305 6418<br>**(Please contact only in emergency situations)** |

## 2. GENERAL INFORMATION

Sunett® (Acesulfame K) is manufactured in a closed production system which meets all legal requirements for environmental protection and plant safety.

A modern computer-supported process routing system controls the production process. The continuous in-process-control shall provide a constant high quality of the operation of the manufacturing process, as well as a constant product quality.

Safety and quality-relevant control points are registered in a database and are frequently monitored. The results of this monitoring are documented in writing and are available if needed. At Celanese Food Ingredients, an HACCP (Hazard Analysis and Critical Control Points) program has been implemented to prevent mistakes and hazards and to achieve a predictable product quality. Employees are checking the critical control points according to schedule.

All raw materials are obtained from authorized suppliers and are checked according to a testing plan.

The operations of the manufacturing process as well as the application of state-of-the-art technology require qualified personnel. A training plan is drawn up every year for each employee. The implementation of the plan is continuously checked.

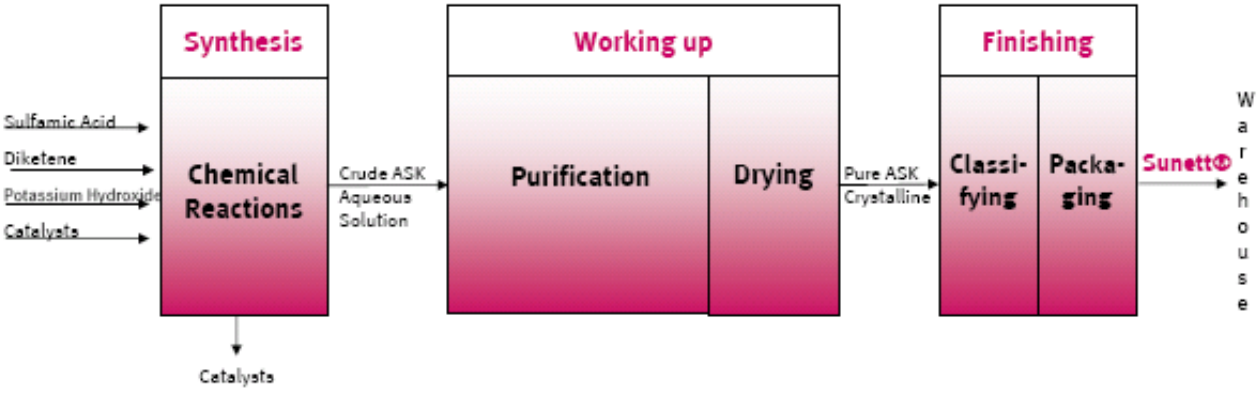
Whereas the production itself is a closed system, the finished product encounters the environment in the filling area for the first time. Consequently, the hygienic demands on employees, plant and packaging are very high.

## 3. PRODUCTION

### 3.1. Production Process of Sunett®

The high-intensity sweetener Sunett® (Acesulfame K) is manufactured synthetically according to a process developed by former Hoechst AG / Celanese Food Ingredients, Germany, through the cyclization of acetoacetamide-N-sulfonic acid with sulphur trioxide and the neutralization with potassium hydroxide.

### 3.2 Production Flow Chart



Celanese Food Ingredients has developed SOPs for plan hygiene. Below there are the most frequent questions:

| **Premises and Facilities** | |
|---|---|
| Are floor drains equipped with Back Flow Prevention Devices? | **Yes** |
| Are there separate areas for receipt, identification, sampling and quarantine of incoming materials, pending release or rejection | **Yes** |
| Are there separate areas for holding rejected materials before further disposition (e.g. return, reprocessing or destruction) | **Yes** |
| Are there separate areas for Storage of released materials | **Yes** |

### 3.3 Source of Sunett®

| ***Source*** | ***YES*** | ***NO*** |
|---|---|---|
| Animal | | X |
| Vegetable | | X |
| Mineral | | X |
| Natural | | X |
| Nature Identical | | X |
| Synthetic | X | |

### 3.4 Manufacture of Sunett® (in Germany only)

Celanese Food Ingredients high-intensity sweetener Sunett® (Acesulfame K) is manufactured in Germany by:

Celanese Production Germany GmbH & Co. KG
Am Unisys-Park 1
65843 Sulzbach (Taunus), Germany

Production Facility:
Sunett® Plant, Building D 483
Industriepark Höchst
65926 Frankfurt / Main, Germany

### 3.5 Ingredient Declaration

| ***Ingredient / Component*** List of all ingredients contained in Sunett® | ***% in Product*** | ***Supplier*** | ***Country Of Origin*** | ***Technical Function*** (e.g. emulsifier, color, processing aid, etc.) |
|---|---|---|---|---|
| Acesulfame K | 100 | Celanese Sales Germany GmbH | Germany | Sweetener |

### 3.6 Change Control System

Changes with respect to our product Sunett® (Acesulfame K) and its production are subject to a Change Control Policy which is part of Celanese Food Ingredients Food Safety & Security Management System. According to such a change control system all changes that affect or may affect the quality / purity of our product are subject to the prior approval by the Celanese Food Ingredients Hazards Analysis Critical Control Point Team (HACCP) led by Celanese Food Ingredients Quality Management.

## 3.7 Lot Size

The lot size of Sunett® (Acesulfame K) is defined as a 48h production. The assignment of lot numbers (a ten digit number) is controlled by SAP. Each lot is linked to specific material numbers. The combination of lot and material numbers guarantee a definite classification and consistent traceability.

## 3.8 Irradiation

Neither the starting materials nor our end product are irradiated during production. This is in compliance with the irradiation legislation of the EU Directive 1999/2/EC as amended, the US FDA regulation 21 CFR 179 and the Japanese Food Sanitation Act.

## 3.9 Pest Control

Celanese Food Ingredients has an active pest control program in place, carried out by an external pest control contractor. The company conducts all control procedures and is completing all relevant documentation.

### Methods

| | |
|---|---|
| Insect control: | UV lights are used to attract insects which then are caught on sticky film. Any insect will be identified and counted. |
| Internal rodent control: | Non-poisoned baited traps are positioned according to available plan. |
| External rodent control: | Secure metal traps with toxic baits are placed externally according to available plan. |

### Checking procedure

All control methods are checked daily by the plant staff and once every month by the pest control company. In case of action required, this task is conducted and documented by the pest control company. If no action is required, the premises will be certified by the pest control company.

### Documentation

The documentation is archived for ten years.

## 3.10 Cleaning Agents

Only cleaning agents which have been approved for use in the food sector are applied. They are diluted according to the manufacturer's specifications and applied according to the regulations of our cleaning plans.

## 3.11 Personal and Plant Hygiene Program

The personal and plant hygiene program conforms to the requirements of the GFSI-recognized FSSC 22000 standard and other food safety standards, e.g. BRC, GMA-Safe etc.

## 3.12 Foreign Object Recognition in the Production of Sunett®

The Sunett® (Acesulfame K) production process takes place within a closed system. A modern, computer-based process control system directs the course of the production process. The filling process of the end product is conducted in special filling rooms according to the Food GMP standard. Thus, the hygienic requirements for people, equipment and packaging materials are high. To exclude the contamination of our product with foreign objects, we have integrated the following measures for the recognition and avoidance of foreign objects into our production and filling processes:

1. Filtration of the liquid sweetener
2. Sieving of the dried product, pore size less than 1000 micron / 18 U.S. Mesh.
3. Permanent magnets (9000 GAUSS) located before filling of final packages
4. Metal detectors located during / after filling process
   The functional check of the metal detector is done daily, before and after filling the manufactured batch.

| | |
|---|---|
| Sensitivity (Cardboard Box): | 2.5 mm stainless steel, 2.2 mm steel, 3.0 mm brass. |
| Sensitivity (Big Bag): | 2.0 mm stainless steel, 1.5 mm steel, 1.8 mm brass. |
| Sensitivity (customized packaging): | 2.5 mm stainless steel, 2.0 mm steel, 3.0 mm brass. |

### 3.13 Traceability / Retained Sample

The European General Law Regulation 178/2002 requires a system for traceability for food ingredients and primary packaging. Celanese Food Ingredients meets these requirements. Traceability is warranted through all stages of purchase of raw materials, packaging materials, production, processing and distribution and allows a complete traceability within only few hours' time.

Celanese Food Ingredients has implemented an identification tool based on SAP in combination with an EAN 128 bar coding system to identify shipment units and trace them back through all stages of the supply chain to the manufacturing and packaging process. Additionally, an internationally readable Serial Shipping Container Code (SSCC) is implemented.

For each manufactured batch we take a retained sample from final product and keep it for 6 years from the date of manufacture.

## 4. PACKAGING AND LABELING

### 4.1 Packaging and Coding

Sunett® (Acesulfame K) size grade A, B and C is filled into 10 and 25kg cardboard boxes with polyamide inner liners which are closed with blue plastic quick fasteners. The polyamide for the inner liner conforms to food legislation governing products in contact with food, including Regulation (EU) 10/2011 and FDA regulations 21 CFR 177.

Sunett® (Acesulfame K) size grade D is filled into 10 and 25kg cardboard boxes with polyethylene inner liners which are closed with blue plastic quick fasteners. The polyethylene for the inner liner conforms to food legislation governing products in contact with food, including Regulation (EU) 10/2011 and FDA regulations 21 CFR 177.

The packaging materials are lot numbered and traceable. The used packaging materials comply with the Directive 1935/2004/EC.

The boxes are labeled on one side with the product name Acesulfame K and underneath with batch number, material number, date of manufacture and best before date. They are sealed with polypropylene adhesive tape which is printed with our company name.

#### Cardboard Box

In order to protect them from humidity and for transport reasons the pallet stacks are covered with a polyethylene stretch film and get secured. To maintain the product quality, we recommend storing the products at ambient temperature (max. 30 °C), dry (max. 65 % relative humidity), in the originally closed packaging and protected from sunlight.

| Packaging | Material | Weight (kg) approx. | Size (mm) |
|---|---|---|---|
| Collapsible cardboard box (10 kg) | Corrugated cardboard | 0.5 | 384 x 180 x 230 |
| Collapsible cardboard box (25 kg) | Corrugated cardboard | 0.8 | 384 x 280 x 280 |
| Pallet CP1* | Chamber dried wood | 19 | 1000 x 1200 x 138 |
| Inliner (10 kg) | HDPE | 0.06 | 290 x 700 |
| Inliner (25 kg) | HDPE | 0.08 | 390 x 800 |
| **Packaging** | **Material** | **Weight (kg) approx.** | **Size (mm)** |
| Inliner (10 kg) | PA | 0.03 | 480 x 700 |
| Inliner (25 kg) | PA | 0.06 | 700 800 |

*Stamped with IPPC (International Plant Protection Convention)

### Big Bag

The big bag is sealed using a numbered seal. The packaging unit is wrapped with a PE stretch film.

| Packaging | Material | Weight (kg) approx. | Size (mm) |
|---|---|---|---|
| Big bag 500 kg | PE/PP | 1.9 | 880 x 880 x 550 |
| Big bag 1000 kg | PE/PP | 2.5 | 880 x 880 x 1020 |

### MOSH/MOHA

Regarding MOSH (Mineral Oil Saturated Hydrocarbons) and MOAH (Mineral Oil Aromatic Hydrocarbons) the packaging materials comply with the current limits set by the Federal Institute for Risk Assessment (BfR).
The inks used for the printing of the packaging material are free of mineral oil compounds. If the packaging material contains a functional barrier layer of plastic, its effectiveness is proved per Art. 13, para. 2, 3 and 4 or Art. 14, para. 2 and 3 of the European regulation no. 10/2011.

## 4.2 Labeling, Storage and Distribution, Storage Conditions

The units which are ready for dispatch can be identified and retraced at any time by the following details:

- Material number
- Lot number
- Product name
- E number
- CAS-No
- Company name and address
- Date of manufacturing
- Best before date
- Country of origin

The finished products are stored at temperature and humidity monitored warehouse under GMP conditions (FSSC-certified). Removal from storage takes place according to the principle of first in first out (FIFO).

Transport and dispatch are carried out exclusively by authorized haulage contractors. The regulations governing the dispatch of food are observed.

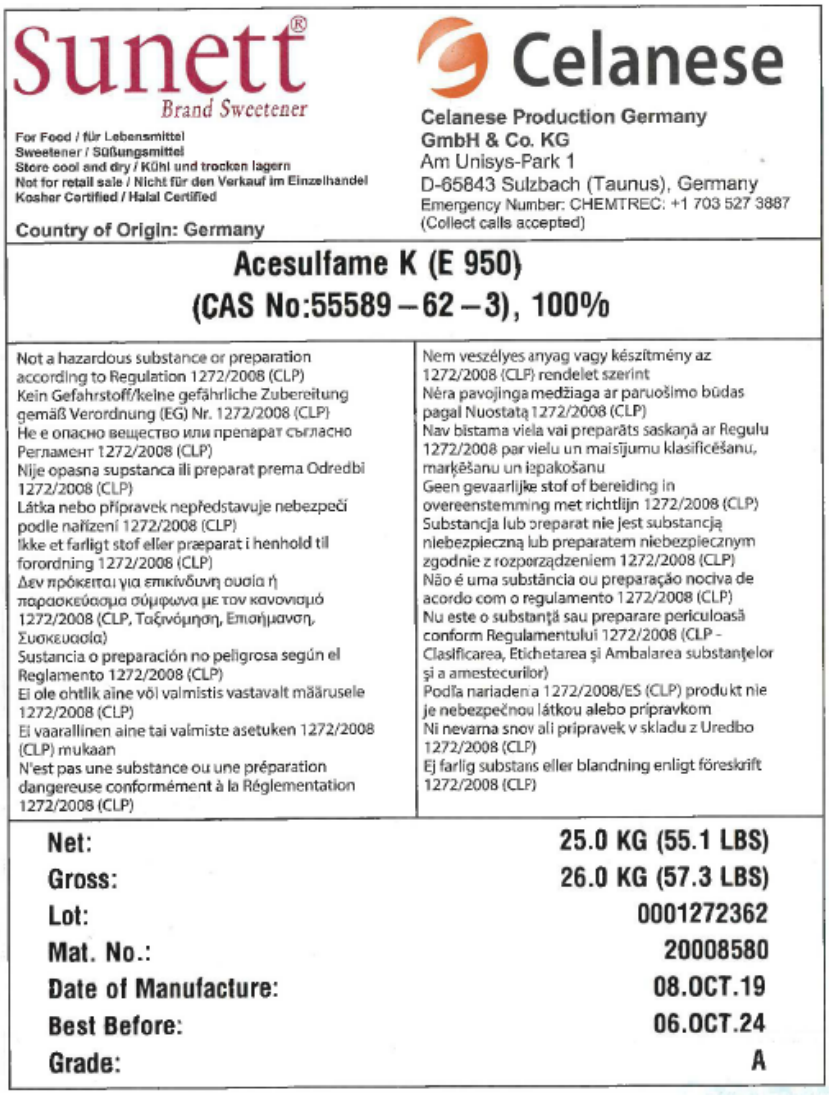
During the storage of our products the following requirements must be fulfilled:

- Ambient temperature: max 30°C
- Dry conditions (max 65 % relative humidity)
- Protection from direct sunlight.

If Sunett® (Acesulfame K) is stored under these conditions in unopened, originally sealed packaging unit, the shelf life is 5 years from date of manufacturing.

## 4.3 Product Label (Example)

Labeling according to Globally Harmonized System of Classification and Labelling of Chemicals (GHS) by the United Nations which was adopted by the EU under Regulation (EC) No 1272/2008 on classification, labeling and packaging of substances and mixtures.



Sunett®
Brand Sweetener

For Food / für Lebensmittel
Sweetener / Süßungsmittel
Store cool and dry / Kühl und trocken lagern
Not for retail sale / Nicht für den Verkauf im Einzelhandel
Kosher Certified / Halal Certified

Country of Origin: Germany

Celanese

Celanese Production Germany
GmbH & Co. KG
Am Unisys-Park 1
D-65843 Sulzbach (Taunus), Germany
Emergency Number: CHEMTREC: +1 703 527 3887
(Collect calls accepted)

**Acesulfame K (E 950)**
**(CAS No:55589–62–3), 100%**

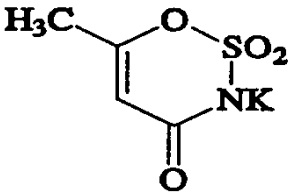
Not a hazardous substance or preparation according to Regulation 1272/2008 (CLP)
Kein Gefahrstoff/keine gefährliche Zubereitung gemäß Verordnung (EG) Nr. 1272/2008 (CLP)
Не е опасно вещество или препарат съгласно Регламент 1272/2008 (CLP)
Nije opasna supstanca ili preparat prema Odredbi 1272/2008 (CLP)
Látka nebo přípravek nepředstavuje nebezpečí podle nařízení 1272/2008 (CLP)
Ikke et farligt stof eller præparat i henhold til forordning 1272/2008 (CLP)
Δεν πρόκειται για επικίνδυνη ουσία ή παρασκεύασμα σύμφωνα με τον κανονισμό 1272/2008 (CLP, Ταξινόμηση, Επισήμανση, Συσκευασία)
Sustancia o preparación no peligrosa según el Reglamento 1272/2008 (CLP)
Ei ole ohtlik aine või valmistis vastavalt määrusele 1272/2008 (CLP)
Ei vaarallinen aine tai valmiste asetuken 1272/2008 (CLP) mukaan
N'est pas une substance ou une préparation dangereuse conformément à la Réglementation 1272/2008 (CLP)

Nem veszélyes anyag vagy készítmény az 1272/2008 (CLP) rendelet szerint
Nėra pavojinga medžiaga ar paruošimo būdas pagal Nuostatą 1272/2008 (CLP)
Nav bīstama viela vai preparāts saskaņā ar Regulu 1272/2008 par vielu un maisījumu klasificēšanu, marķēšanu un iepakošanu
Geen gevaarlijke stof of bereiding in overeenstemming met richtlijn 1272/2008 (CLP)
Substancja lub preparat nie jest substancją niebezpieczną lub preparatem niebezpiecznym zgodnie z rozporządzeniem 1272/2008 (CLP)
Não é uma substância ou preparação nociva de acordo com o regulamento 1272/2008 (CLP)
Nu este o substanță sau preparare periculoasă conform Regulamentului 1272/2008 (CLP - Clasificarea, Etichetarea și Ambalarea substanțelor și a amestecurilor)
Podľa nariadenia 1272/2008/ES (CLP) produkt nie je nebezpečnou látkou alebo prípravkom
Ni nevarna snov ali pripravek v skladu z Uredbo 1272/2008 (CLP)
Ej farlig substans eller blandning enligt föreskrift 1272/2008 (CLP)

| | |
|---|---|
| **Net:** | **25.0 KG (55.1 LBS)** |
| **Gross:** | **26.0 KG (57.3 LBS)** |
| **Lot:** | **0001272362** |
| **Mat. No.:** | **20008580** |
| **Date of Manufacture:** | **08.OCT.19** |
| **Best Before:** | **06.OCT.24** |
| **Grade:** | **A** |

## 5. PROPERTIES

### 5.1 Structural Formula of Sunett®




### 5.2 Analytical Laboratory

Our laboratory is situated at the Industriepark Höchst, Frankfurt, Germany and belongs to the Celanese Group. Quality Management (QM) department is independent from production and responsible for the whole quality control process. The laboratory conducts analytical tasks for incoming raw material, in-process testing and for the final release of Sunett® (Acesulfame K). Release of product is controlled by SAP.

| **Analytical Testing & Subcontracting (Question & Answers)** | |
|---|---|
| Are all analytical testing performed by an internal laboratory?<br>Yes, excluding microbiological and heavy metal testing conducted by an external laboratory.<br><br>Does your company utilize Third Parties to complete a portion of or all of the GMP related activities?<br>Yes, these are according to the requirements of food GMP. | |
| Calibration | In-house |
| Testing of in-coming materials | In-house |
| Testing of in-process materials | In-house |
| Final release testing | In-house (and/or external laboratory) |
| Microbiological Testing | External accredited laboratory |
| Heavy Metal Testing | External ISO certified laboratory |

**Retain sample policy:**
We store retain samples of Sunett® (Acesulfame K) for 6 years from date of manufacture.

## 5.3 Microbiological Properties

Sunett® (Acesulfame K) is produced synthetically and is virtually free from microorganisms. Any viable microorganisms are killed at temperatures occurring during production and subsequent drying. Sunett® is virtually free from water; therefore, it is very unlikely that microorganisms can grow on Sunett®.

Sunett® (Acesulfame K) is packed under hygienic conditions and all people involved in packing have been properly trained and wear required protective clothing.

Microbiological testing is conducted by Institute Fresenius, an external accredited laboratory according to the requirements of Ph. Eur. and USP-NF.

**Microbiological Specification of Sunett® (Acesulfame K)**

| Property | CFU |
|---|---|
| Total Mesophilic Count | < 10 in 1 g |
| Yeasts | < 10 in 1 g |
| Molds | < 10 in 1 g |
| Enterobacteria | < 10 in 1 g |
| Staphylococcus aureus | negative in 1 g |
| Pseudomonas aeruginosa | negative in 1 g |
| Escherichia coli | negative in 1 g |
| Salmonellae | negative in 10 g |

## 5.4 Food Grade Compliance

The food quality of Sunett® fulfills the purity requirements of the FAO/WHO/CODEX/JECFA, those of the US Food Chemicals Codex (FCC) 12th edition, the JSFA 9th edition and the EU Commission Regulation 231/2012.

Acesulfame K has been adopted by the FAO/WHO Codex Alimentarius Commission as food additive and approved in the US according to 21CFR 172.800, Japan according to the Japanese Food Sanitation Act and the EU according to the Regulation (EC) No 1333/2008 and currently is going through re-evaluation in accordance with Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008.

### 5.4.1 Product Specification Food Grade

Please contact Celanese Sales Germany GmbH for the official product specification documents.

**Sunett ® - Food Grade - Chemical and physical properties**

| | |
|---|---|
| **Synonyms** | **Acesulfame potassium salt (Acesulfame K)** |
| **Definition** | |
| Chemical name: | Potassium salt of 6-methyl-1.2.3-oxathiazin-4(3H)-one-2.2-dioxide |
| CAS number: | 55589-62-3 |
| E number: | E 950 |
| EINECS number: | 259-715-3 |
| Chemical formula: | $C_4H_4NO_4SK$ |
| Relative molecular mass: | 201.24 |
| **Description** | Odourless, white, crystalline powder having an intensively sweet taste<br>Approximately 200 times as sweet as sucrose.<br>Very soluble in water (approx. 270 g/L at 20 °C); less soluble in acetone (approx. 0.8 g/L at 20 °C) and ethanol (approx. 1 g/L at 20 °C). |
| **Identification** | |
| Ultra-violet absorption: | UV-Maximum 227 ± 2 nm (solution of 0.01 g/L in water) |
| Test for potassium: | Positive |
| **Purity** | |
| Assay: | 99.5 % to 100.5 % of $C_4H_4NO_4SK$, on dry weight basis |
| Loss on drying: | Not more than 0.2 % (105 °C, 2 hours) |
| pH-value: | 5.5 - 7.5 (1 % water solution) |
| Assay of potassium: | 17 % - 21 % |
| 5-Cl-Acesulfame K | Not more than 2 ppm |
| Organic Impurities | Not more than 20 ppm of UV active components |
| Filtration test: | No residues (100g dissolved in 1000 mL water / filtration over 0.45 µm membrane filter) |
| Heavy metals: | Not more than 5 ppm (expressed as lead) |
| Lead: | Not more than 0.1 ppm |
| Arsenic: | Not more than 0.1 ppm |
| Cadmium | Not more than 0.1 ppm |
| Selenium: | Not more than 0.2 ppm |
| Mercury | Not more than 0.01 ppm |
| Fluoride: | Not more than 1 ppm |
| Sulphate: | Not more than 20 ppm |
| **Particle size distribution** | |
| Type A: | Min. 95 % smaller than 1000 microns |
| Type B: | Min. 95 % smaller than 600 microns |
| Type C: | Min. 95 % smaller than 355 microns |
| Type D: | Min. 95 % smaller than 100 microns |
| **Shelf life** | 5 years from date of manufacture<br>provided that the product is stored in the originally closed packaging protected from sunlight, at ambient temperature (max. 30 °C) and dry (max. 65 % relative humidity) conditions |

Sunett® (Acesulfame K) conforms also to the specifications published by FAO/WHO/CODEX/JECFA, those of the US Food Chemicals Codex, of the JSFA and/or the EC. Any existing legal restrictions for the use in foods, drugs and cosmetics must be observed by users of Sunett®.



® = registered trademark PSuA0400 October 2019

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Germany
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Fax: + +49 (0)69 45009- 58294
Email: foodingredients-emea@celanese.com
Web: www.celanese.com/food-ingredients/about-us.aspx

Sunett® Brand Sweetener

## 5.4.2 Certificate of Analysis Food Grade (example)

# Certificate of Analysis

Sunett® particle Size A; 25 kg box

**Cert Issue Date:** 13 Nov 2019

**Material No.:** 20008580
**Produced at:** Frankfurt am Main
**Produced on:** 26 Sep 2019
**Best before date:** 24 Sep 2024
**Country of origin:** Germany

**Batch 0001267611**

| Characteristic | (Method) | UoM | Value | |
|---|---|---|---|---|
| Sunett® is the brand name for Celanese Food Ingredients high-intensity sweetener Acesulfame K. | | | | |
| Abs. max. (in Water) | (UV) | nm | 227,3 | 225,0 - 229,0 |
| Appearance | VISUAL | | white, crystalline powder | |
| Assay | (HPLC) | % | 100,1 | 99,5 - 100,5 |
| Colour | VISUAL | | Pass | |
| Fluoride | (IC) | ppm | < limit of detection | 0,1 - 1,0 |
| Heavy metals (calc. as lead) | (Limit-Test) | ppm | < 5 | max. 5 |
| Identity Acesulfame | (UV) | | Pass | |
| Identity Potassium | (FAO / WHO) | | Pass | |
| Loss on drying (2h/105°C) | (FAO / WHO) | % | 0,02 | max. 0,20 |
| Loss on drying (3h/105°C) | (EP) | % | 0,02 | max. 0,20 |
| Odour | (sensoric) | | odourless | |
| pH-value (1% solution) | (potentiometric) | | 7,1 | 5,5 - 7,5 |
| Potassium | (IC) | % | 19,4 | 17,0 - 21,0 |
| Potassium acetate | (IC) | % | < 0,5 | max. 0,5 |
| Residue of filtration | (Filtration) | | no residue of filtration | |
| 5-Cl-Acesulfame-K | (HPLC) | ppm | < 2 | max. 2 |
| Organic Impurities | (HPLC) | ppm | < 20 | max. 20 |
| Acetylacetamide (Imp. A) | (HPLC) | ppm | < limit of detection | 0,5 - 1,0 |
| Sulfate | (IC) | ppm | < limit of detection | max. 20,0 |
| The following values are based upon statistical evaluation and are adhered to with each batch. | | | | |
| Arsenic | (ICP MS) | ppm | < limit of detection | 0,02 - 0,10 |
| Lead | (ICP MS) | ppm | < limit of detection | 0,02 - 0,10 |
| Cadmium | (ICP MS) | ppm | < limit of detection | 0,02 - 0,10 |
| Mercury | (AAS) | ppm | < limit of detection | max. 0,01 |
| Selenium | (ICP MS) | ppm | < limit of detection | max. 0,20 |
| Escherichia coli | (PH.EUR) | | neg. / 1g | |
| Pseudomonas aeruginosa | (PH.EUR) | | neg. / 1g | |
| Salmonella bacilli | (PH.EUR) | | neg. /10g | |
| Staphylococcus aureus | (PH.EUR) | | neg. / 1g | |
| Enterobacteriaceae | (PH.EUR) | | < 10 CFU / 1g | |
| Total mesophilic counts | (PH.EUR) | | < 10 CFU / 1g | |
| Yeasts | (PH.EUR) | | < 10 CFU / 1g | |
| Moulds | (PH.EUR) | | < 10 CFU / 1g | |

## 5.5 Pharma Grade Compliance

Sunett® is conforming to the monographs published by the European Pharmacopoeia, US Pharmacopoeia and Japanese Pharma Excipient list. Following please find our Celanese Specification and example of the Certificate of Analysis.

### 5.5.1 Product Specification Pharma Grade

Please contact Celanese Sales Germany GmbH for the official product specification documents.

**Sunett ® - Pharma Grade Type A-D - Chemical and physical properties according to European Pharmacopoeia 10.0* and US Pharmacopoeia 43-NF 38***

| | |
|---|---|
| **Synonyms** | **Acesulfame potassium salt (Acesulfame K)** |
| **Definition** | |
| Chemical name: | Potassium salt of 6-methyl-1.2.3-oxathiazin-4(3H)-one-2.2-dioxide |
| CAS number: | 55589-62-3 |
| E number: | E 950 |
| EINECS number: | 259-715-3 |
| Chemical formula: | $C_4H_4NO_4SK$ |
| Relative molecular mass: | 201.24 |
| **Description** | Odourless, white, crystalline powder having an intensively sweet taste<br>Approximately 200 times as sweet as sucrose.<br>Very soluble in water (approx. 270 g/L at 20 °C); less soluble in acetone (approx. 0.8 g/L at 20 °C) and ethanol (approx. 1 g/L at 20 °C). |
| **Identification** | |
| Ultra-violet absorption: | UV-Maximum 227 ± 2 nm (solution of 0.01 g/L in water) |
| IR-spectrum | Positive (complies with reference spectrum) |
| Test for potassium: | Positive |
| **Pharma specific tests** | |
| Appearance of solution: | Clear and colourless |
| Acidity: | Not more than 0.2 mL of 0.01 M sodium hydroxide per 4 g in 20 mL carbon dioxide-free water |
| Alkalinity: | Not more than 0.2 mL of 0.01 M hydrochloric acid per 4 g in 20 mL carbon dioxide-free water |
| Organic impurities: | |
| Acetylacetamide (Impurity A): | Not more than 1 ppm |
| 5-Cl-Acesulfame K (Impurity B): | Not more than 2 ppm |
| Unspecified Impurities (PH Eur): | Not more than 20 ppm of UV active components |
| Total impurities (PH Eur): | Not more than 20 ppm of UV active components |
| Residual solvents: | Not more than 5 ppm (Class 1-3 Residual Solvents according to PH Eur / USP) |
| **Purity** | |
| Assay: | 99.5 % to 100.5 % of $C_4H_4NO_4SK$, on dry weight basis |
| Loss on drying: | Not more than 0.2 % (105 °C, 3 hours) |
| pH-value: | 5.5 - 7.5 (1 % water solution) |
| Assay of potassium: | 17 % - 21 % |
| Filtration test: | No residues (100g dissolved in 1000 mL water / filtration over 0.45 µm membrane filter) |
| Heavy metals: | Not more than 5 ppm (expressed as lead) |
| Lead: | Not more than 0.1 ppm |
| Arsenic: | Not more than 0.1 ppm |
| Cadmium | Not more than 0.1 ppm |
| Selenium: | Not more than 0.2 ppm |
| Mercury | Not more than 0.01 ppm |
| Fluoride: | Not more than 1 ppm |
| Sulphate: | Not more than 20 ppm |

| | |
|---|---|
| **Particle size distribution** | |
| Type A: | Min. 95 % smaller than 1000 microns |
| Type B: | Min. 95 % smaller than 600 microns |
| Type C: | Min. 95 % smaller than 355 microns |
| Type D: | Min. 95 % smaller than 100 microns |
| **Microbiology** | |
| Total mesophilic counts | < 10 KBE in 1 g |
| Yeasts | < 10 KBE in 1 g |
| Moulds | < 10 KBE in 1 g |
| Enterobacteriaceae | < 10 KBE in 1 g |
| Staphylococcus aureus | negative in 1 g |
| Pseudomonas aeruginosa | negative in 1 g |
| Escherichia coli | negative in 1 g |
| Salmonellae | negative in 10 g |
| **Shelf life** | 5 years from date of manufacture provided that the product is stored in the originally closed packaging protected from sunlight, at ambient temperature (max. 30 °C) and dry (max. 65 % relative humidity) conditions |

Sunett® Pharma Grade meets the requirements of the European Pharmacopoeia and US Pharmacopoeia.
Acesulfame K is also registered by the US FDA 21CFR 172.800 - DMF-No. 87 33 / Type IV.

Sunett® (Acesulfame K) conforms also to the specifications published by FAO/WHO/CODEX/JECFA, those of the US Food Chemicals Codex, those of the JSFA and/or the EC. Any existing legal restrictions for the use in foods, drugs and cosmetics must be observed by users of Sunett®.



* amended version PSuPhA0999 February 2020

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## 5.5.2 Certificate of Analysis Pharma Grade (example)

# Certificate of Analysis

Sunett® Particle Size A Pharma Grade; 25 kg box

**Cert Issue Date:** 13 Nov 2019

**Material No.:** 20008581
**Produced at:** Frankfurt am Main
**Produced on:** 12 Jul 2019
**Best before date:** 10 Jul 2024
**Country of origin:** Germany

**Batch 0001237821**

| Characteristic | (Method) | UoM | Value | |
|---|---|---|---|---|
| Abs. max. (in Water) | (UV) | nm | 227,0 | 225,0 - 229,0 |
| Alkalinity | (EP) | | Pass | |
| Acidity | (EP) | | Pass | |
| Appearance | VISUAL | | white, crystalline powder | |
| Appearance of Solution | (EP) | | clear and colourless | |
| Assay | (HPLC) | % | 99,9 | 99,5 - 100,5 |
| Colour | VISUAL | | Pass | |
| Fluoride | (IC) | ppm | < limit of detection | 0,1 - 1,0 |
| Heavy metals (calc. as lead) | (Limit-Test) | ppm | < 5 | max. 5 |
| Identity Acesulfame | (UV) | | Pass | |
| Identity Potassium | (FAO / WHO) | | Pass | |
| Identity Potassium | (USP) | | Pass | |
| IR spectrum | (EP, IR) | | Pass | |
| Loss on drying (2h/105°C) | (FAO / WHO) | % | 0,03 | max. 0,20 |
| Loss on drying (3h/105°C) | (EP) | % | 0,03 | max. 0,20 |
| Odour | (sensoric) | | odourless | |
| Residual solvents | (ICH, GC) | ppm | < 5 | 2 - 5 |
| Dichloromethane | (ICH, GC) | ppm | < limit of detection | 2 - 5 |
| pH-value (1% solution) | (potentiometric) | | 7,0 | 5,5 - 7,5 |
| Potassium | (IC) | % | 19,2 | 17,0 - 21,0 |
| Potassium acetate | (IC) | % | < 0,5 | max. 0,5 |
| Residue of filtration | (Filtration) | | no residue of filtration | |
| Chromatographic purity (USP) | (HPLC) | ppm | < 2 | max. 2 |
| | | | | |
| Impurity B/ 5-Cl-Acesulfame K (EP) | (HPLC) | ppm | < 2 | max. 2 |
| Unspecified impurities (EP) | (HPLC) | ppm | < 20 | max. 20 |
| Total impurities (EP) | (HPLC) | ppm | < 20 | max. 20 |
| Acetylacetamide (Imp. A) | (HPLC) | ppm | < limit of detection | 0,5 - 1,0 |
| Sulfate | (IC) | ppm | < limit of detection | max. 20,0 |
| Arsenic | (ICP MS) | ppm | < limit of detection | 0,02 - 0,10 |
| Lead | (ICP MS) | ppm | < limit of detection | 0,02 - 0,10 |
| Mercury | (AAS) | ppm | < limit of detection | max. 0,01 |
| Selenium | (ICP MS) | ppm | < limit of detection | max. 0,20 |
| Cadmium | (ICP MS) | ppm | < limit of detection | 0,02 - 0,10 |

The following values are based upon statistical evaluation and are adhered to with each batch.

| | | |
|---|---|---|
| Escherichia coli | (PH.EUR) | neg. / 1g |
| Pseudomonas aeruginosa | (PH.EUR) | neg. / 1g |
| Salmonella bacilli | (PH.EUR) | neg. /10g |
| Staphylococcus aureus | (PH.EUR) | neg. / 1g |
| Enterobacteriaceae | (PH.EUR) | < 10 CFU / 1g |
| Total mesophilic counts | (PH.EUR) | < 10 CFU / 1g |
| Yeasts | (PH.EUR) | < 10 CFU / 1g |
| Moulds | (PH.EUR) | < 10 CFU / 1g |

### 5.5.3 Compliance to ICH Q3C Guideline for Residual Solvents

Each batch Sunett® Pharma Grade is tested with GC for Residual Solvents including Triethylamine and Dichloromethane.
According to EP/USP General Chapter <467> Organic Volatile Impurities/Residual Solvents and the ICH Harmonised Tripartite Guideline for residual solvents (EMA/CHMP/ICH/82260/2006) in the updated version hereby we confirm, that no Class 1 solvents are likely to be present in Sunett ® Pharma Grade.
Dichloromethane, as a Class 2 solvent is used during the manufacturing process. Results are on our Certificate of Analysis. Limit for Dichloromethane per Celanese specification is 5 ppm, level found mostly < 1 ppm (Level of detection). Limit according to ICH < 600 ppm.
Triethylamine, as a Class 3 solvent is used during the manufacturing process according to GMP. Limit for Triethylamine per Celanese specification is 5 ppm. Triethylamine is limited according to ICH with GMP.

### 5.5.4 Compliance regarding ICH Q3D Guideline on Elemental Impurities

Sunett® (Acesulfame K) is fully in compliance with the ICH Q3D Guideline EMA/CHMP/ICH/ 353369/2013 (“Guideline on elemental impurities”) and its implementation in USP-NF and Ph Eur.

### 5.5.5 Specification Limits for Residues of Metal Catalysts or Metal Reagents

In accordance to the Guideline EMEA/CHMP/SWP/4446/2000 (European Agency for the Evaluation of Medicinal Products Evaluation of Medicines for Human Use ) no metal catalysts and/or metal reagent are being used in our Sunett® (Acesulfame K) production process.

## 5.6 Allergens

| **Allergens (Question & Answers)** | |
|---|---|
| Does the product contain any animal or plant-derived ingredients? | No,<br>Sunett® is manufactured synthetically without using animal or plant derived ingredients. |
| Does the product contain any ingredients identified as allergens? | No,<br>Sunett® is manufactured synthetically without using ingredients identified as allergens. |
| Is a cross-contamination possible? | No,<br>Sunett® is manufactured synthetically in a dedicated plant. A potential cross-contamination during mixing, filling, packaging and storage can be ruled out because none of the allergens listed below nor products containing allergens as listed below are handled during manufacture and storage in the production side. |

Sunett® (Acesulfame K) complies with the EU Regulation 1169/2011, the US Food Allergen Labeling and Consumer Protection Act and the Japanese Food Labeling Act as part of the Food Sanitation Act, and does not contain any ingredients listed as following:

- Cereals containing gluten namely wheat, rye, barley, oats, spelt, kamut or their hybridised strains, and products thereof
- Crustaceans and products thereof
- Eggs and products thereof
- Fish and products thereof
- Peanuts and products thereof
- Soybeans and products thereof
- Milk and products thereof (including lactose)

- Nuts, namely: almonds (*Amygdalus communis* L.), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoinensis* (Wangenh) K. Koch), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia or Queensland nuts (*Macadamia ternifolia*), and products thereof
- Celery and products thereof
- Mustard and products thereof
- Sesame seeds and products thereof
- Sulphur dioxide and sulphites
- Lupin and products thereof
- Molluscs and products thereof
- Fabaceae or Leguminosae including chick peas
- Other materials with high allergenic potential

Furthermore, Sunett® (Acesulfame K) does not contain any of the following substances or products thereof:

| | | | |
|---|---|---|---|
| garlic | buckwheat | coconut | seasonings |
| millet | stone fruits | pine nut | rice |
| vanillin | glutamate | benzoic acid | maize |

## 5.7 Genetically Modified Organisms (GMO)

Sunett® (Acesulfame K) contains no genetically modified organisms (GMO) or components and is not obtained from genetically modified crops.

The starting materials used in the production of our Sunett® have not been manufactured by the use of genetically modified micro-organisms. Thus, our product is not obliged to be labeled according to EU Regulations 1829/2003 and 1830/2003 respectively nor according to the Japanese Food Sanitation Act.

## 5.8 Nutritional Information

Sunett® (Acesulfame K) has the following nutritional values:

| **Based on 100 g Sunett®** *according to regulation (EC) No 1924/2006* | |
|---|---|
| Energy value (kcal/KJ) | 0 |
| Total Carbohydrates (g)<br>• Dietary fiber<br>• Sugars/Added Sugars | 0<br>0<br>0 |
| Fat (g) | 0 |
| Cholesterol (mg) | 0 |
| Protein (g) | 0 |
| Sodium (g) | 0 |
| Potassium (g) | 19.6 |
| Calcium (g) | 0 |
| Iron | 0 |
| Vitamin D | 0 |

## 5.9 Vegan Statement

Sunett® (Acesulfame K) is manufactured without the use of animal matter or products derived from animal origin. At no stage of production and processing, use has been made of products of animal origin including:

- ingredients (including additives, carriers, aromas, fragrances, flavorings and enzymes) or
- processing aids or
- substances which are not additives but are used in the same way and with the same purpose as processing aids

This comprises especially:

- No meat or any other slaughter products, e.g. offal
- No fish or any other marine animals
- No eggs
- No honey
- No milk
- No wax of animals such as wool fat/lanoline, beeswax or shellac
- No fur, no leather, no silk
- No royal jelly
- No colouring agents of animal origin
- No substances, which were bleached with animal charcoal
- No substances, which were clarified with animal substances such as gelatine or fish bladder
- No substances manufactured, obtained or produced from the above-mentioned substances.

In addition, the raw materials used for the manufacture of Sunett® (Acesulfame K) are Sulfamic Acid, Diketene and Sulphur Trioxide. The production process can be divided into the following steps:

- Chemical synthesis
- Crystallization from water
- Drying
- Packaging
- Storage
- Shipment

## 5.10 Absence of Specific Substances

### 5.10.1 Non-containing Dioxins, PCBs or PAHs

Our products comply to Commission Regulation (EC) No. 1881/2006 and do not contain Dioxins (PCDD / FCDF) or PCBs nor polycyclic aromatic hydrocarbons.

### 5.10.2 Mycotoxin Data

Sunett® (Acesulfame K) is produced synthetically without use of agricultural raw materials, which excludes possible contamination by mycotoxins.

| Mycotoxin | Does the product conform to legislative maximum levels? | | |
|---|---|---|---|
| | YES | NO | N/A |
| Total Aflatoxins | | | X |
| Aflatoxin B1 | | | X |
| Ochratoxin A | | | X |
| Patulin (Apples only) | | | X |

### 5.10.3 Nitrofen

Sunett® (Acesulfame K) does not contain any Nitrofen.

### 5.10.4 Latex

Latex is not used during the manufacturing process. Therefore Sunett® (Acesulfame K) does not contain any Latex.

### 5.10.5 Compliance with California Proposition 65

Proposition 65 includes chemicals known to the state of California to cause cancer or reproductive toxicity. Sunett® (Acesulfame K) is not carcinogenic or reproductive toxicant, therefore it is not listed in the Proposition 65 list and does not require a warning label.

### 5.10.6 Compliance with Toxic Substance Control Act (TSCA)

Acesulfame K as a food additive (sweetener) is regulated by USFDA under the Federal Food, Drug, and Cosmetic Act (FFDCA), therefore Sunett® (Acesulfame K) is exempted from the TSCA Inventory.

### 5.10.7 Non-containing Substances mentioned in the Prohibited List of WADA

None of the substances mentioned in the World Anti-Doping Agency (WADA) code of prohibited substances are present in Sunett® (Acesulfame K). In addition, Sunett® is manufactured synthetically in a dedicated plant, therefore a cross-contamination with any substances mentioned in the WADA code of prohibited substances can also be ruled out.

### 5.10.8 Palm Oil

Palm oil, palm kernel oil and/or palm oil derivatives are not used in the manufacturing process, furthermore, these are not stored in our manufacturing plant nor in our warehouse. So a cross-contamination can be ruled out.

### 5.10.9 Transmitting Animal Spongiform Encephalopathy / Certificate of Suitability

Sunett® (Acesulfame K) is manufactured synthetically in a dedicated plant, not used for any other purpose. All raw materials used are of petrochemicals and inorganic chemicals and no animal/ ruminant material is used.

Therefore, guideline EMA/410/01 (as revised) on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products and a Certificate of Suitability are not applicable for our products.

### 5.11 Animal Non-Testing Declaration

Sunett® (Acesulfame K) has not been subjected to animal testing for cosmetic or toiletry applications by our company or tested on its behalf after January 1 st, 1998, nor does it contain any material from animal origin.

## 6. QUALITY AND FOOD SAFETY MANAGEMENT

### 6.1 DIN EN ISO Certification

Celanese Food Ingredients, including the Sunett® plant, has been certified according to the requirements of DIN EN ISO 9001:2015, DIN EN ISO 14001:2015 + Cor 1:2009, both since 1997, FSSC 22000, version 4.1 (DIN EN ISO 22000:2005, ISO/TS 22002-1:2009 and additional FSSC 22000 requirements) and Food Defense of IFS Food Standard, version 6 of chapter 6. The current certificates are available at http://www.celanese.com/food-ingredients/products/Sunett/media-literature.aspx

### 6.2 Good Manufacturing Practice (GMP) of Sunett®

The manufacture, filling, packaging and storage of our products are conducted according to the regulations of Current Good Manufacturing Practice (GMP) in Manufacturing, Packing, or Holding Human Food (21 CFR Part 110 and 21 CFR Part 117). Thus, Celanese Food Ingredients provides a very high standard of food safety and hygiene during all processing, filling and storage steps. Our safety and hygiene system were inspected according to the requirements of FSSC 22000 standard.

### 6.3 HACCP

The Celanese Food Ingredients Hazards Analysis Critical Control Point ( HACCP) system is based upon the principles of the HACCP system of Codex Alimentarius (ALI-Norm 97/13, Annex 2, created by FAO/WHO), an internationally accepted standard for food and food safety. It also fulfills the HACCP requirements of British Retail Consortium Standard (BRC) and ISO 22.000. Additionally HACCP is part of the external GFSI recognized FSSC 22000 certification and the Celanese Food Ingredients HACCP system and plan is external audited yearly.

| | |
|---|---|
| PRINCIPLE 1: | Conduct a hazard analysis |
| PRINCIPLE 2: | Determine the Critical Control Points (CCP's) |
| PRINCIPLE 3: | Establish critical limit(s) |
| PRINCIPLE 4: | Establish a system to monitor control of the CCP |
| PRINCIPLE 5: | Establish the corrective action to be taken when monitoring indicates it that a particular CCP is not under control |
| PRINCIPLE 6: | Establish procedures for verification to confirm that the HACCP system is working effectively |
| PRINCIPLE 7: | Establish documentation concerning all procedures and records appropriate to these principles and their application |

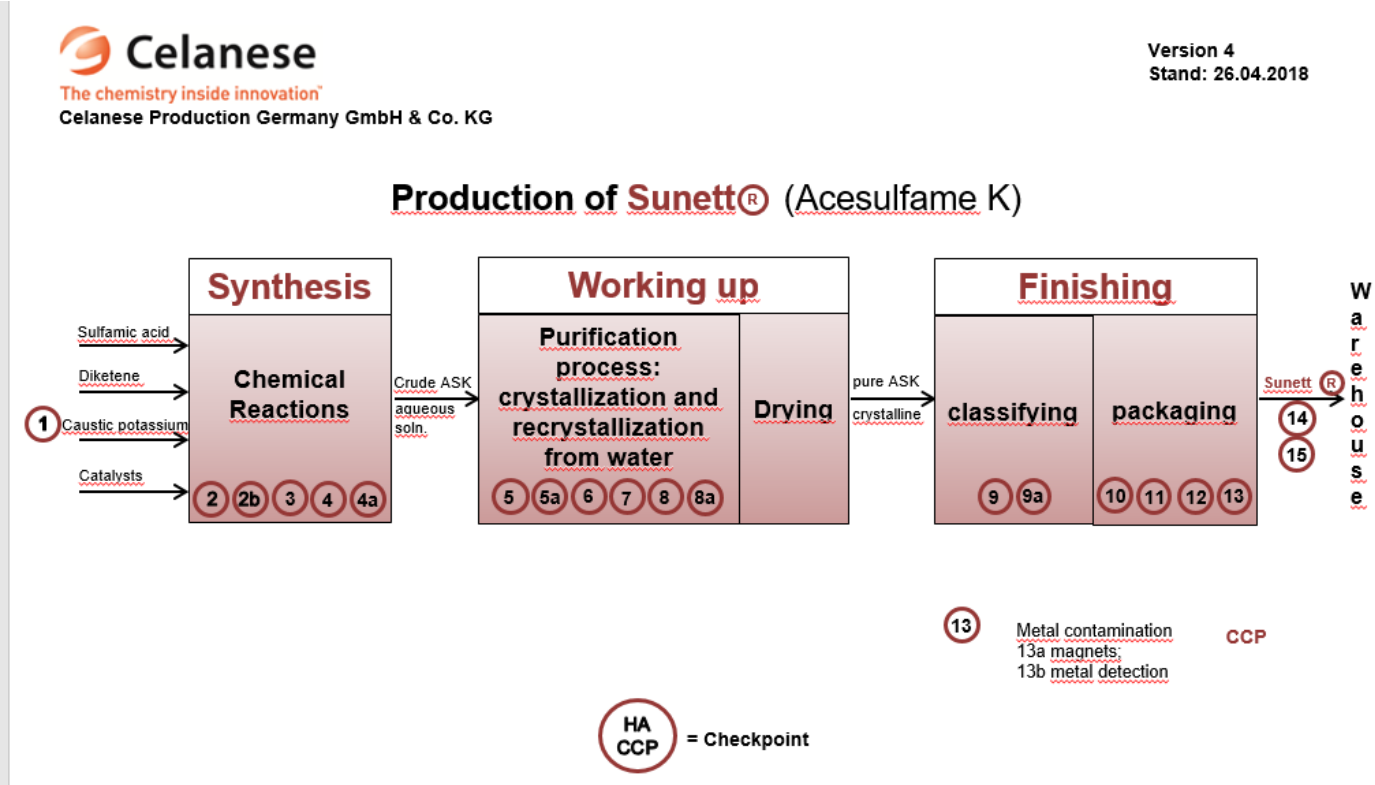
A HACCP team is responsible for implementing and maintaining the Celanese Food Ingredients HACCP system. They have to check if the HACCP system is working correctly and effectively. In relation to this, audits of the HACCP system are conducted by internal auditors at least once a year. The Board of Management and HACCP teams are kept informed about the results by an audit report as well as during the yearly management review.

The Celanese Food Ingredients HACCP system is validated routinely by the multi-disciplinary team. Within this scope, comprehensive reviews of particular hazard analysis and HACCP plan are conducted. The defined critical limit of particular Critical Control Points (CCP's) and Quality Control Points (QCP's) are validated and fitted accordingly, if appropriate. The CCP's and QCP's are checked on accuracy. In the case of changes and/or new information, it will be necessary to check whether the HACCP system and/or hazard analysis will also need to be changed. If so, an adoption of the HACCP plan and system will be conducted and documented.

According to the HACCP concept, testing plans and regulations are established to detect and prevent errors. This procedure maintains a high standard of hygiene and safety:

- Spatial separation of the production and the filling areas
- Regular cleaning according to approved cleaning SOPs
- Personal hygiene
- Protective filtering
- Metal detectors / metal separators / sieves
- Glass and plastic policy
- Hygiene controls of the filling area
- Microbiological control

The determined particular Critical Control Point (CCP's) in the Sunett® production is metal detection and magnetic separation at the end of the filling process, see flow-chart:



## 6.4 Shelf Life Certificate Sunett® and Stability Testing Program (IPEC)

The shelf life of Sunett® (Acesulfame K) is

**5 years from date of manufacture**

provided that the product is stored in the originally closed packaging, protected from sunlight, at ambient temperature (max. 30 °C) and dry (max. 65 % relative humidity) conditions.

**Stability Testing Program** is done according to the "Good Manufacturing Practise Guide for Bulk Pharmaceutical Excipients" of the International Pharmaceutical Excipients Councils (IPEC, version 2017, Chapter 8.2.4.7).

It is a documented testing and evaluation program in place to assess the stability characteristics of the excipient Sunett® (Acesulfame K). The results of the stability testing are used in determining appropriate storage conditions and re-evaluation or expiration dates. The testing program is on-going and includes the following:

- The number of lots, sample sizes and test intervals
- Storage conditions and test methods sufficient to indicate stability
- Storage of the excipient Sunett® (Acesulfame K) in original closed packaging.

## 6.5 Supplier Approval

Only approved suppliers are allowed to deliver packaging and raw materials. Suppliers will be approved according to the Standard Operation Procedure (SOP) for supplier approval which includes questionnaires, audits, samples/ analytical control, product specification, etc. In addition, the incoming packaging and raw materials are controlled according to the SOP for packaging and raw material testing SOP´s. All approved suppliers are listed and communicated to the proper functions.

## 6.6 Sustainability

Celanese is a registered supplier on EcoVadis for Corporate Social Responsibility (CSR). Our manufacturing site in Frankfurt is certified according to Sedex standard (also CSR), ISO 50001 (Energy Management System) and ISO 14001 (Environmental Management System). Official certificates are available on http://www.celanese.com/food-ingredients/products/Sunett/media-literature.aspx.

## 6.7 Kosher Certification

The processing, filling and packaging are regularly inspected by an authorized and globally recognized Rabbinate. The current Kosher Lamehadrin (Parve) and Passover certificate is available on http://www.celanese.com/food-ingredients/products/Sunett/media-literature.aspx.

## 6.8 Halal Certification

The processing, filling and packaging are regularly inspected by an authorized and globally recognized Halal organization. The current Halal certificate is available on http://www.celanese.com/food-ingredients/products/Sunett/media-literature.aspx.

## 6.9 Food Safety and Security Management System

Celanese Food Ingredients is committed to produce high quality and safe food additives. Official certificates are available on http://www.celanese.com/food-ingredients/products/Sunett/media-literature.aspx.

FSSC 22000*, version 4.1 (DIN EN ISO 22000:2005, ISO/TS 22002-1:2009 and additional FSSC 22000 requirements)

ISO 9001:2015 (Quality Management System)

ISO 14001:2015 (Environmental Management System)

ISO 22000:2005 (Food Safety Management System)

Food Defense of IFS Food (version 6 at chapter 6)

GMP (Good Manufacturing Practices)

GDP (Good Distribution Practices)

HACCP (Hazard Analysis and Critical Control Point)

EC Directive 178/2002 (Traceability)

USA Food Safety Modernization Act (2011)

Risk Management

Control program for food safety and hygiene

Traceability of the product and its used raw and auxiliary materials and packaging

materials up to 6 years

Purchase of raw, auxiliary and packaging materials only from approved suppliers

Customer audits upon request

Complete control of the manufacturing process

Crisis Management

Emergency Availability 24 hours 7 days a week

*FSSC 22000 is one of the most important GFSI-recognized certification programs for the Food industry. GFSI (Global Food Safety Initiative) is a global, industry wide set of standards and requirements that a certification program must meet (https://mygfsi.com).

## 7. QUESTIONS & ANSWERS

| | |
|---|---|
| Do you have a document that describes your quality systems, e.g. Quality Manual? | Yes |
| To whom does QA report within your organization? | To the Vice President Quality Celanese |
| Is QA independent of production? | Yes |
| Do you have an internal auditing system (i.e. self-inspection program)? | Yes |
| If so, please describe. | According to the Internal audit protocol |
| Do you have a Supplier Evaluation Prog? | Yes |
| Describe the method of evaluation (i.e. audit by mail etc.). | Questionnaire, audit, specification, analytical raw material release, etc. |
| Do you have an approved list of suppliers and which department is responsible for approving and disapproving suppliers? | Yes, Quality Management, Product Stewardship, Production & Purchasing |
| In case you supplied a customer with a defective product, would you or your distributor notify the customers and is there a recall procedure in place? | Yes, system for recall in place, a responsible person is available 24h / 7days<br>Emergency number: + 49 (0)69 305 6418 |
| If so, please describe how products are recalled. | According to the Crisis Management System in place |
| Describe your procedure to handle customer complaints? | SAP Complaint Management System |
| Are complaints investigated and records maintained on file? | Yes |
| Are deviations and non-conformances investigated, documented and filed? | Yes |
| Do you have a formalized documentation control system in place? | Yes |
| If yes, please describe this system. | Documentation Control System in place with approval documents |
| How long do you keep the analytical and the production records? | 6 years |

| | |
|---|---|
| Who is responsible for the release of your product into the market? | Quality Manager |
| Does QA perform a batch record review? If so, is it part of your release decision? | Yes, done by Quality Management. |
| Does the product comply with the TSE Note for Guidance EMEA/410/01? | N/A*. Sunett® is manufactured synthetically without using animals as source of material. |
| Does the product comply with the ICH Q3C Guideline (Residual Solvents)? | Yes, Dichloromethane (Class 2) is used during production, results for “Residual solvent” mentioned in CoA for Sunett® Pharma Grade |
| Does the product comply with German Guideline "Aflatoxin VerbotsV dated 19.07.00"? | N/A*. Sunett® (Acesulfame K) is produced synthetically without use of agricultural raw materials, which excludes possible contamination by mycotoxins. |

**Analytical Control (QC – Quality Control)**

| | |
|---|---|
| Is QC independent of production? | Yes |
| What kind of laboratory facilities do you have? | Analytical laboratory |
| Do you use any contract laboratory?<br>If so, for which tests? | Yes<br>1) Institute SGS Fresenius, Taunusstein, Germany:<br>• Microbiological testing<br>2) CLAS laboratory, Industriepark Höchst, Germany:<br>• Heavy metals testing<br>• Residual Solvents testing |
| Have you qualified/ evaluated these contract laboratories? | Yes |
| Do you release incoming raw materials based on Supplier Certificates of Analysis (CoA)? | Yes |
| If so, do you perform any testing on your own? | Yes |
| Do you have procedures that define the control of raw materials? | Yes |
| Are there formal written procedures in place for all analyses performed? | Yes |

N/A = Not applicable

| | |
|---|---|
| Are the analytical methods used validated? | Yes |
| Please provide product specifications and test methods of the product in question. | Test methods are mentioned on CoA |
| Do you analyze according to the current Pharmacopoeia Testing Methods? | Yes, our methods are validated against the official Ph. Eur. and USP-NF methods. |
| If yes, according to which one, e.g. Ph. Eur., USP-NF? | Both Ph. Eur. and USP-NF |
| Will you provide a Certificate of Analysis (CoA) with each shipment, including actual analytical data to customers? | Yes |
| How long is the product stable and how do you assess the shelf life? (i.e. are stability-testing data for the product in question available?) | 5 years from date of manufacture, stability data according to IPEC guidelines |
| Which storage or handling conditions do you recommend for the product? (temperature, humidity) | Store in the originally closed packaging, at ambient temperature (max. 30 °C), dry conditions (max. 65 % relative humidity) and protected from sunlight. |
| Who performs the sampling and who performs the testing of:<br>▪ raw materials<br>▪ in-process checks and<br>▪ finished products | Trained personal |
| Do you keep records of all samples entering the laboratories? | Yes |
| Do these records include:<br>▪ date sample received<br>▪ identity of samples<br>▪ testing results<br>▪ date sample taken and<br>▪ name of person who took sample | Yes |
| Do you have procedures defining the handling of quality documents regarding<br>▪ update<br>▪ approval and<br>▪ use and archiving | Yes |
| How are Out-Of-Specification (OOS) results investigated and documented in the laboratories? | Via SAP system, process in place |
| Describe your procedure for analytical reagent standardization. | SOP in place |

| | |
|---|---|
| How do you assure that testing equipment is calibrated at appropriate intervals? | SOP in place |
| Describe any electronic data processing systems, which are used in the laboratory (i.e. LIMS). | SAP QM module |
| Are these systems validated? | Yes |
| What kind of water do you use in the laboratory? | Demineralised water |
| Please state the physical/ chemical and the micro-biological quality of this type of water. | Pharma filter in place, micro checks routinely done |
| How often do you control this type of water? | Once per month |

**Production and Process**
**General Questions**

| | |
|---|---|
| To whom does the production report within your organization? | To the Site Director Industrial Park Hoechst, Celanese |
| Do you manufacture/handle products of high activity or toxicity such as β-lactams, other antibiotics, cytotoxins or pesticides on the site? | No |
| Do you manufacture other products than the one being questioned in your manufacturing facility (Monoplant?) | No, it is a dedicated plant for Sunett® (Acesulfame K) production |
| Are all the manufacturing steps for the stated material performed at this site (including purification and packaging, etc.)? | Yes |
| Did you work out risk analysis of production processes using tools like HACCP? | Yes |
| If so, please give document reference number. | DQS certificate FSSC 22000<br>Registration No. 003122 FSSC V4 |
| Do you issue a batch record for each batch/lot manufactured? | Yes |
| Is non-conforming final product ever mixed with conforming product to bring it into specification? | No |
| Is there a formal procedure for production deviations in place? | Yes |
| Who does approve such deviations? | SOP in place |
| Are room and equipment log books available? | Yes |

| | |
|---|---|
| Do all product containers bear identification labels, e.g. stating batch/lot number, product name, etc.? | Yes |
| How do you mark the status of your manufacturing equipment (e.g. <cleaned>, <calibrated>, <in use>)? | SOP in place |
| Describe the segregation and control of approved, quarantined and rejected material. | SAP positive release, red and green labels, separated storage areas |
| Do you have segregated dispensing areas for different raw materials? | Yes |
| Is there a maintenance and preventive maintenance program for all relevant pieces of equipment in place? | Yes |
| Describe your procedure for instrument calibration. | SOP in place |
| Are there written procedures and schedules covering these calibrations? | Yes |
| Are rest and eating areas separate from other areas? | Yes |
| Do you have a pest control program against rodents, vermin and other animals? | Yes, monitored monthly according to pest control program |

**Product related Questions**

| | |
|---|---|
| Is your production process continuous or batch? | Batch= 48h production |
| Do you use dedicated equipment for the production of the product in question? | Yes |
| Describe the convention used for batch or lot numbering. | SAP code |
| Does the lot number represent one homogenous production run? | Yes |
| Are there validated yield ranges for the manufacturing process? | Yes |
| Are deviations investigated and documented? | Yes |
| Are there cleaning procedures in place for each area and piece of equipment? | Yes |
| Are your manufacturing and cleaning processes validated? | Yes |
| Are manufacturing and cleaning procedures approved by QA? | Yes |
| Are there separate dust extraction facilities in areas where dust is generated? | N/A |
| Is compressed air filtered and dried?<br>Please indicate type of filters | Yes, Pharma filter |
| Do you clean the ventilation and dust extraction systems according to a defined plan and with which frequency? | Yes, according to SOP / cleaning schedule |
| Please state the different types of water used in production. | Only water according to German “Trinkwasserverordnung” (tab water regulation) purified and filtered |
| Please state the physical/ chemical and the micro-biological quality of this type of water. | According to German “Trinkwasser-verordnung” (tab water regulation) |
| How often do you control this type of water? | Monthly |

| | |
|---|---|
| Describe any electronic data processing systems which are used in production. | SAP system<br>Production control system |
| Is the product directly filled into the shipping pack after production and then stored until shipment or is the product first stored in containers and only filled into the shipping pack just before shipment? | Directly filled into final packaging. We have a contracted warehouse in Worms, Germany where the final product is stored until distribution. |
| What kind of containers do you use (fiber drums, inner linings etc.)? | Cardboard box with PA inner liner or 500/1000kg Big Bags<br>Packaging materials are delivered with protective cover. |
| Are there special pre-cautions (e.g. nitrogen, desiccant for packing)? | No |
| What measures have you implemented to make sure that the product is not contaminated by foreign matters?<br>Do you sieve the material before final packing (if so, what mesh size)? Do you use magnetic bars to remove metal particles? | Sieve, metal detection, permanent magnets<br><br>Yes, depending on grade we use magnetic stainless steel 1000µm (18mesh), 600µm (30 mesh) und 355µm (45 mesh). |
| Under what conditions do you store the final product (temperature, humidity)? | Ambient temperature (max 30° C), dry (rel. humid max 65%) and protected from sunlight |
| How do you make sure that Customer Purchase Orders, packaging and shipping requirements are followed? | Input into SAP |
| Can you pack to order (Yes/No) or do you have standard pack sizes? | Standard pack size |
| Is each bag/container labeled with the name of the product and lot no.? | Yes |
| Will each box/big bag on a pallet bear the lot no. and/or description clearly visible? | Yes |
| Do you put different batches of one product on one pallet? | No, only one batch per pallet |
| Do you keep records of all shipments to customers, including batch number and quantity? | Yes |

## 8. ATTACHMENT

### 8.1 ICH Q3C (R7) - Residual Solvents

We confirm that Sunett® (Acesulfame K) complies with the Guideline EMA/CHMP/ICH/82260/2006.

| | |
|---|---|
| Supplier Trade Name | Sunett® (Acesulfame K) |
| Manufacture by | Celanese Production Germany GmbH & Co. KG<br>Am Unisys-Park 1<br>65843 Sulzbach (Taunus)<br>Germany |

**Class 1 Solvents**

The product in question was manufactured (including all manufacturing steps) with the use of Class 1 Solvents?

☐ Yes ☒ No

**Class 2 Solvents**

The product in question was manufactured (including all manufacturing steps) with the use of Class 2 Solvents?

☒ Yes ☐ No

| Name of Class 2 Solvent | Maximum Concentration [ppm] mostly below | Celanese specification [ppm] | Complies with ICH Guideline Q3C for Residual Solvents |
|---|---|---|---|
| Dichloromethane | 1 (limit of detection) | 5 | Yes |

**Class 3 Solvents**

The product in question was manufactured (including all manufacturing steps) with the use of Class 3 Solvents?

☒ Yes ☐ No

| Name of Class 3 Solvent | Maximum Concentration [ppm] | Celanese specification [ppm] | Complies with ICH Guideline Q3C for Residual Solvents |
|---|---|---|---|
| Triethylamine | < 5 | 5 | Yes |

## 8.2 Table and Test Report according to ICH – Q3D-Guideline for Elemental Impurities

Sunett® is fully in compliance with the ICH Q3D Guideline. None of the elements mentioned in this guideline is added intentionally during production. Nevertheless, Sunett® is analyzed regularly per AAS (Mercury) and ICP-MS (others) on different elements, the reports can be received on request. Following an overview:

| Element | Class | Oral concentration acc ICH Q3D (R1), Table A2.2. [µg/g] | Intentionally added | If not intentionally added but likely to be present | LOD (of used Method) [µg/g] | CFI Specification [µg/g] |
|---|---|---|---|---|---|---|
| Cd | 1 | 0,5 | No | No | 0,01 | 0,10 |
| Pb | 1 | 0,5 | No | No | 0,02 | 0,10 |
| As | 1 | 1,5 | No | No | 0,02 | 0,10 |
| Hg | 1 | 3 | No | No | 0,01 | 0,01 |
| Co | 2A | 5 | No | No | 0,02 | 0,10 |
| V | 2A | 10 | No | No | 0,02 | 0,02 |
| Ni | 2A | 20 | No | No | 0,02 | 0,02 |
| Tl | 2B | 0,8 | No | No | 0,02 | 0,02 |
| Au | 2B | 10 | No | No | 0,02 | 0,02 |
| Pd | 2B | 10 | No | No | 0,10 | 0,10 |
| Ir | 2B | 10 | No | No | 0,10 | 0,10 |
| Os | 2B | 10 | No | No | 0,10 | 0,10 |
| Rh | 2B | 10 | No | No | 0,10 | 0,10 |
| Ru | 2B | 10 | No | No | 0,10 | 0,10 |
| Se | 2B | 15 | No | No | 0,20 | 0,20 |
| Ag | 2B | 15 | No | No | 0,02 | 0,02 |
| Pt | 2B | 10 | No | No | 0,10 | 0,10 |
| Li | 3 | 55 | No | No | 0,10 | 0,10 |
| Sb | 3 | 120 | No | No | 0,02 | 0,10 |
| Ba | 3 | 140 | No | No | 0,02 | 0,10 |
| Mo | 3 | 300 | No | No | 0,02 | 0,10 |
| Cu | 3 | 300 | No | No | 0,02 | 0,10 |
| Sn | 3 | 600 | No | No | 0,20 | 0,20 |
| Cr | 3 | 1100 | No | No | 0,02 | 0,10 |

## 8.3 GMO Questionnaire

Does the product conform to the current EU food regulations?

☒ Yes ☐ No

Does the product contain genetically modified material?

☐ Yes ☒ No

Has the product been tested to be free of genetically modified material (i.e. < 1%)?

☐ Yes ☒ No

Has the product been sourced from non-genetically modified raw materials by means of segregation measures (i.e. only non-GM materials in the entire supply chain)?

☒ Yes, only non-GM materials in the entire supply chain ☐ No