

TATA CHEMICALS EUROPE LTD (TCEL)

WINNINGTON

SODIUM BICARBONATE

PRODUCTION

HACCP STUDY (*Issue 8*)

Summary for customers

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1. HACCP Team and Scope

This HACCP study has been carried out to ensure that all Sodium Bicarbonate (SB) manufactured for food, animal feed and pharmaceutical use and sold to FCC, EP and USP specifications is produced in accordance with the Food Safety Act 1990, the Food Hygiene Regulation EU 852/2004, the Feed Hygiene Regulation EU 183/2005 and The Codex Alimentarius and therefore meets the requirements of the BRC Technical and FEMAS Standards.

A review of the HACCP study (Issue 6) was carried out during April 2014 by a team consisting of the following members:

SB Production Specialist (HACCP Team Leader)	Rosie Cox.
Head of SB Operations	Christina McMinn
Production Team Leader	Ian Clarke
SB Manufacturing Manager	John Foster
SB FP & Warehouse Manager	Les Ross
SB Mechanical Plant Engineer	Pete Simpson
Quality Manager	Chris Daniels
SB Development Chemist	Denise Boardman
SB Plant Technologist	Joe Evans

The mix of people listed ensured the appropriate product specific knowledge and expertise in the areas of manufacture, storage and despatch were represented.

The scope of the study covered incoming raw materials (Sodium carbonate, CO₂, Additives & packaging), conversion to and separation of grades of sodium bicarbonate through to packing, storage and despatch of final product to customer. The Sodium Bicarbonate plant for the purpose of the study was split into 6 areas

- Wetside Operations (new sections added in 2014 review –see below).
- Dust Plant and No 1 Packpoint.
- No 10 Packpoint and bulk loading.
- DMS (Dry manufacturing side).
- Milling Plant.
- DMS packing.
- Product Despatch.

During the HACCP study review the plant flow diagrams were checked in detail for each area and modified accordingly. This ensured that the flow diagrams reflect a true representation of the current plant configuration.

Changes to HACCP Plan at March 2013 Review:

HACCP Team members updated

Changes made in Rev1 to Iss6 (re milling PFR SB) incorporated

Change to 2.0 Description of Product – change description of process raw materials to reflect 2014 changes.

New sections added to represent raw material supply changes 2014: Section 4.2a Sodium Carbonate Dissolving and Liquor Recycle and Section 4.2b Gas Supply and Recycle

Name changes where missed in Issue 6 (Brunner Mond to Tata Chemicals Europe)

Filter Aid change — no change to risk. Requirement for Food Grade added to control measures in this document

Hazard Categories

The study covered the following classes of hazards - microbiological, chemical and foreign body (e.g. metal, glass/plastic, wood, pests, packaging). Sodium bicarbonate is a dry, inorganic, alkaline product, so the microbiological risk was considered to be low. Allergens were considered not to be an issue within Sodium Bicarbonate products due to the wholly inorganic chemical nature of sodium bicarbonate synthesis and ingredients. The following extract is offered as a company statement to Sodium Bicarbonate customers:.

SODIUM BICARBONATE

Free From

Sodium Bicarbonate as supplied by Tata Chemicals Europe is free from any of the following substances:

Meat and animal derivatives	Fructose
Nuts and nut products	Added sugar
Milk and dairy products (inc lactose & casein)	Saccharin
Fish and products thereof	BHA/BHT
Peanuts and products thereof	Mustard
Soybean and products thereof	Benzoate
Eggs and products thereof	Yeast
Sesame seeds and products thereof	Corn
Crustaceans and products thereof	Cocoa
Lupins and products thereof	Glutamine
Molluscs and products thereof	Hydroxybenzoate
Celery and products thereof	Aspartame
Sulphur dioxide and sulphites at concentrations above 10mg/kg or 10mg/l expressed as SO ₂	
Cereals containing gluten (wheat, rye, barley, oats, spelt, kamut and hybrids)	
E102, E110, E122, E123, E124, E151, E129, E131, E132, E160d	

Sodium Bicarbonate as supplied by Tata Chemicals Europe does not contain any substances having allergenic properties for which labelling is required, as defined in Directive 2003/89/EC

The HACCP team considered temporal hazards and concluded there are no seasonal or day/night factors affecting sodium bicarbonate food safety.

2. Description of Product and its uses.

Sodium Bicarbonate is a white, odourless, crystalline solid completely soluble in water and is the mildest sodium alkali. It is manufactured on a large scale by Tata Chemicals Europe to a high degree of purity (European and United States Pharmacopoeia) and in a range of particle sizes to meet the wide variety of applications.

Nomenclature and key chemical properties:

Chemical name	Sodium hydrogen carbonate
Common names	Sodium bicarbonate, baking soda
Chemical formula	NaHCO ₃
Molecular weight	84.00
Acid equivalent	1g NaHCO ₃ = 0.434g HCL
CO ₂ equivalent	100% NaHCO ₃ = 52.3 % CO ₂

Sodium bicarbonate is of low toxicity and is not classified as dangerous for supply or conveyance. Dust may cause discomfort on inhalation or in case of eye contact although there are no known effects of long-term exposure. Chemical purity of sodium bicarbonate above 99% is required to meet EU legislative requirements for food additive purity (Regulation EU 231/2012). No likely contaminants of sodium bicarbonate produced in TCEL process present a food safety hazard.

Two naturally occurring raw materials - salt and limestone - are used to synthesise sodium carbonate in Tata Chemicals Europe's ammonia soda process.. Prior to 2014, the sodium carbonate was supplied in solution (known as DCB liquor) from the Winnington Ammonia Soda plant, but now the sodium carbonate is supplied in solid form from Tata's Lostock Ammonia Soda plant. The CO₂ was also previously supplied 40%v/v from on-site kilns, but Carbon Dioxide and Nitrogen are now purchased in liquefied form and blended to provide suitable composition. The sodium carbonate is dissolved and the solution is saturated with carbon dioxide gas causing precipitation of crystals of sodium bicarbonate. The crystalline slurry is centrifuged and dried in an atmosphere containing carbon dioxide which prevents reversion to sodium carbonate. Many different grades are then extracted by a combination of air classification, micronising and sieving. Additives are added to selected grades in order to enhance flow or other characteristics.

All grades, except General Purpose, are available in 25 kg paper sacks having 2-ply lamination with moisture barrier, heat-sealed closure which additionally is taped to provide tamper-evidence and ink jet print of traceability data. Sacks are supplied on 4 way entry wooden pallets with dimensions of 1200 by 1000 mm (for 25kg sacks) or 1100 by 1100 mm (for IBC's). Additional to this, for a small number of customers, bespoke customer specific pallets are also used. A moisture barrier separates the top of the pallet and the bottom layer of sacks. The loaded pallets are then individually stretch-hooded. In the Mill valve sacks are used and traceability is ensured using self adhesive printed date labels.

All grades are also available in woven propylene FIBC's which may be polyethylene-lined or unlined, some of which are bottom valve discharged. FIBC's are individually palletised and hooded with polyethylene.

Sodium bicarbonate should be stored in cool dry conditions. Degradation due to heat or moisture uptake does not cause any food safety hazard and so shelf-life recommendations do not relate to food safety issues. Sodium bicarbonate is a chemically stable product and so no ultimate expiry date is defined.

Product uses

In addition to traditional applications such as baking of confectionery, antacid and effervescent pharmaceutical preparations, novel applications are continually being developed. The product is an essential ingredient in a wide range of applications including haemodialysis, explosion suppression, dental products, PVC and elastomer foam-blowing, animal nutrition, shot blast cleaning, flue gas treatment and household detergents. Broad categories of usage are:

Food products

Baking

A major use is as a leavening or raising agent in baking applications. During baking the CO₂ is released causing the dough to rise. Tata Chemicals Europe's Powder Fine, Extra Fine, FFQ, Microfine and Fine granular grades are typical grades produced for this application.

Beverages

There is a wide variety of drinks in which sodium bicarbonate and an acid constituent such as citric acid are formulated as a dry mix. Adding water produces an effervescent drink.

Food processing

Here it is used as a buffering agent or mild alkalising agent in general processing. Examples include use in sherbet fruit sweets and alkalising of cocoa beans.

Sodium bicarbonate is approved for use as a food additive at Quantum Satis level (EU reg 1129/2011). There are no restrictions on suitability for any specific categories of customer/consumer.

Pharmaceuticals

The bicarbonate ion is a vital component of human physiology and finds applications in proprietary and ethical medicines. A common use is in effervescent salines.

It is also a suitable pH buffer in pharmaceutical processes and is used as a constituent in some toiletry products. Sodium Bicarbonate is widely used in haemodialysis treatment.

Animal Foodstuffs

Sodium bicarbonate is used in ruminant and poultry diets.

Flue Gas Treatment

Sodium Bicarbonate is used in the acid abatement process of waste flue gases from waste incineration systems and chemical processing facilities.

3. Prerequisites

The Sodium Bicarbonate Plant HACCP Study is supported by the following prerequisites.....

Pre-Requisite	Procedure ref
Good Manufacturing Procedures	Procedure for Good Manufacturing Practice (NW/SB/GMP/001)
Pest Control Contract	GMP Guidelines (NW/SB/GMP/001.6.5)
Cleaning	Procedure for the Cleaning & Housekeeping of NW Sodium Bicarbonate Plant (NW/SB/GMP005)
Glass / Plastics Register	Procedure for Control of Glass, Plastics, Brittle Materials and Wood
Procurement, Supplier Approval Procedures	Procurement Practice Note 8
Raw Material Specifications	Procedure for the Purchase of Quality Critical Goods and Services (BM/PUR/OP/001)
Finished Product Specifications	Customer Agreed Specifications (BM/QAS/QAP/009) Sodium Bicarbonate Product Specifications (QMS Manual 29)
Training (GMP, Food Hygiene and basic HACCP principles)	Procedure for Good Manufacturing Practice (NW/SB/GMP/001) Procedure for Training and Training Records (BM/QAS/QAP/021)

4.1 Overview of Sodium Bicarbonate Plant

Production Risk Zones

BRC Global Standard for Food Safety Issue 6 defines four different risk zones within the processing and storage facilities with corresponding levels of hygiene and segregation. In increasing order of control requirements, the zones are Enclosed Product Area, Low Risk – open product area, High Care – open product area and High Risk – open product area. A decision tree is provided in Appendix 2 of the Standard to guide definition of zones.

Each of the factory areas for production of Food Grade Sodium Bicarbonate (4.2 – 4.8 on the Overview diagram below) has been considered separately against the decision tree. In each case the answer to the Step1 question (Are products or ingredients within the area open to the environment ie neither packaged nor fully enclosed in tanks or pipes?) was “No”. Consequently, **all areas of the Sodium Bicarbonate Plant are defined as Enclosed Product Areas.**

The product is at very low risk of microbiological contamination due to its dry, alkaline, inorganic nature. The factory is dedicated to synthesis of this single chemical and so the risk of chemical contamination is also low. Enclosure of the process stream in reaction vessels, driers, transfer belts silos and direct filling into sacks and FIBCs minimises the risk of physical contamination. Extra hygiene controls are applied in Area 4.7 DMS Packing because some invasive actions such as sampling and magnet inspections associated with CCP take place but the product remains enclosed during packing.

5.0 Summary of CCP's

5.1 Wetside Plant

PROCESS STEP		HAZARD	CONTROL MEASURE	CRITICAL LIMITS	MONITORING PROCEDURES	CORRECTIVE ACTION
Step	Description					
7 (CCP1)	Centrifuge	Hydraulic fluid leakage from Centrifuge to product.	In line sampling. Food grade oil. Scheduled maintenance	Creeper Bicarb Clarity 94% min. Adherence to maintenance programme.	Twice a shift Creeper sample taken & tested for clarity ^o Maintenance records ⁺	Designate material to No 10 silo according to SB/OP/003 Sec 5.13 Review schedule.
8d (CCP2)	Gas heating	Survival of bacteria / bacterial spores due to under heating	Heat gas leaving heater to 105°C min	Min 105 °C	Continuous temperature record ^o Low temperature alarm	Adjust temperature and Designate material to No 10 silo according to SB/OP/003 Sec 5.13

+ - Maintainer
o - Wetside Controller

5.2 No 10 Pack Point & Bulk Loading

PROCESS STEP		HAZARD	CONTROL MEASURE	CRITICAL LIMITS	MONITORING PROCEDURES	CORRECTIVE ACTION
Step	Description					
3.1.0 (CCP3)	Screening sifter (IBC)	Oversize contamination / metal from breakdown of screen	Pre & every 10 te inspection and regular cleaning	Sifter intact	Visual inspection at beginning and during campaign*	Replace sifter Designate material according to SB/OP/003 Sec 5.13
3.1.1 (CCP4)	Screening (magnets) (IBC)	Metal contamination	Pre & every 10 te Inspection & regular cleaning.	No excessive build up	Visual inspection at beginning and during campaign*	Designate material according to SB/OP/003 Sec 5.13 Clean magnet
3.2.1 (CCP5)	Screening sifter (RBL)	Oversize contamination / metal from breakdown of screen	Pre & post inspection.	Sifter intact	Visual inspection at beginning and end of loading*	Replace sifter Designate material according to SB/OP/003 Sec 5.13
3.2.2 (CCP6)	Screening (magnets) (RBL)	Metal contamination	Pre & post inspection.	No excessive build up	Visual inspection at beginning and end of loading*	Designate material according to SB/OP/003 Sec 5.13 Clean magnet

* - Packer

5.3 Dust Plant & No1 PPT

PROCESS STEP		HAZARD	CONTROL MEASURE	CRITICAL LIMITS	MONITORING PROCEDURES	CORRECTIVE ACTION
Step	Description					
2.4 (CCP7)	Screening Sifter	Oversize material / metal contaminating product following breakdown of screen	Inspection & regular cleaning as per schedule.	Sifter intact	Once per shift inspection and clean #	Replace sifter Designate material according to SB/OP/003 Sec 5.13
2.5 (CCP8)	Screening (magnets)	Accumulated metal contamination falling into product	Inspection & regular cleaning as per schedule.	No excessive build up	Visual inspection once per shift #	Designate material according to SB/OP/003 Sec 5.13 Clean magnet

- Grader

5.4 Milling Plant

PROCESS STEP		HAZARD	CONTROL MEASURE	CRITICAL LIMITS	MONITORING PROCEDURES	CORRECTIVE ACTION
Step	Description					
5.2 (CCP9)	Screening (sifter)	Oversize material / metal contaminating product following breakdown of screen	Pre & every 5te inspection maintenance	Sifter intact	Visual inspection at beginning and during campaign *	Designate material according to SB/OP003 5.13 Replace sifter
5.2.1 (CCP10)	25kg sack filling Screening (magnets)	Accumulated metal contamination falling into product	Inspection & regular cleaning as per schedule	No excessive build up	Visual inspection at beginning and end of campaign *	Designate material according to SB/OP003 5.13 .. Clean magnet
5.2.2 (CCP11)	IBC Screening (magnets)	Accumulated metal contamination falling into product	Inspection & regular cleaning as per schedule	No excessive build up	Visual inspection at beginning and end of shift *	Designate material according to SB/OP003 5.13 . . Clean magnet

* - Packer (miller)

5.5 DMS Plant

PROCESS STEP		HAZARD	CONTROL MEASURE	CRITICAL LIMITS	MONITORING PROCEDURES	CORRECTIVE ACTION
Step	Description					
11a (CCP12)	Screens	Breakdown of screens. Slider plastic contamination. Seal failure.	Analysis of grades. Product quality checks. Grill inspections. Training of operators and maintainers pre requisite.	No contamination. Grills intact. Training of operators.	Once per shift inspection of chute grills # Sampling & analysing product for particle size distribution 6 per shift.	Designate material according to SB/OP003 5.13

- Grader

5.6 DMS Packing

PROCESS STEP		HAZARD	CONTROL MEASURE	CRITICAL LIMITS	MONITORING PROCEDURES	CORRECTIVE ACTION
Step	Description					
1.0 (CCP 13)	Transfer (belts)	Physical contamination from broken or failing belt	Routine visual inspection Maintenance when indicated by inspection	Intact belt – no splits	Visual inspection during production ⁺	Designate material according to SB/OP003 5.13 Replace belt.
1.2.4 (CCP 14)	Metal detection (25kg line)	Metal from plant	Metal detection procedures	Fe – 2.8mm Non Fe – 3.0mm S/S - 3.4mm	Test sticks at start & end of campaign [*]	Designate material according to SB/OP003 5.13
1.4.1 (CCP 15)	Screening magnets + mesh IBC line.	Debris from magnets and mesh	Inspection & cleaning	No excessive build up	Visual inspection at beginning and end of campaign [*]	Designate material according to SB/OP003 5.13 Clean magnet
1.2.0 (CCP16)	Screening magnets + mesh 25kg line.	Debris from magnets and mesh	Inspection & cleaning	No excessive build up	Visual inspection at beginning and end of campaign [*]	Designate material according to SB/OP003 5.13 Clean magnet

* - Packer (despatcher for step 19)

+ - Maintainer