JONES DAY

AVOCATS – ADVOCATEN

4, RUE DE LA RÉGENCE • REGENTSCHAPSSTRAAT 4

1000 BRUSSELS, BELGIUM

TELEPHONE: 32.(0)2.645.14.11 • FACSIMILE: 32.(0)2.645.14.45

October 12, 2023

TO WHOM IT MAY CONCERN

Dear Applicant,

Re: Sorbitol and Maltitol Joint REACH Registration Group ('SMJRRG')

This document contains the relevant information for purchasing a letter of access 'LoA' for joining the joint REACH registration for the substance:

CAS 68425-17-2 SYRUPS, HYDROLYZED STARCH, HYDROGENATED; DESCRIPTION: A COMPLEX COMBINATION OBTAINED BY THE CATALYTIC HYDROGENATION OF HYDROLYZED STARCH SYRUPS. IT CONSISTS PRIMARILY OF SORBITOL, MALTITOL, MALTOTRIITOL, AND HYDROGENATED OLIGO AND POLYSACCHARIDES

prepared by the **SMJRRG**. In addition, this PDF provides the relevant earlier SIEF communications issued by the Lead Registrant / Consortium. Please note that the Consortium management was transferred from McKenna Long & Aldridge LLP to **JONES DAY** in 2014, with still the same person (Ursula Schliessner) in charge after the transfer. The pre-2014 documents are therefore under the McKenna Long & Aldridge LLP name.

If you wish to purchase a LoA, please fill in the next pages **'LOA APPLICATION FORM' and pdf them to the attention of the Reach Team: reachteam@jonesday.com**. You will then receive a pre-payment notice by email for payment of the LoA price. As soon as we have received your payment in full, we will confirm that payment has been received and you will receive the joint submission token and any other necessary documentation (Chemical Safety Report, Guidance on Safe Use as the case may be) that you may need to join the Joint Submission via the ECHA REACH-IT portal (please see the ECHA Guidance on joining the Joint Submission). Potential registrants have to submit their individual parts (Article 10 (a) (i), (ii), (iii) and (x)) of the IUCLID 6 registration dossiers separately to ECHA by the relevant deadline.

Invoices for paid LoA fees will be issued by the Consortium on a periodic basis as soon as a sufficient number of LoAs have been processed and pre-paid.

If you have any questions, please do not hesitate to contact:

Ursula Schliessner at uschliessner@jonesday.com / Telephone +32-2-645 1460

Letter of Access ('LoA') Application Form

Sorbitol and Maltitol Joint Reach Registration Group ('SMJRRG')

LoA will be issued per group of companies. Please fill in the application form only ***once*** for all affiliated group companies.
(*To be filled in and emailed back to ReachTeam@jonesday.com*)

NOTE:
**** By completing and sending the LoA application form to Jones Day, you shall be considered as having accepted the terms of the respective SIEF Agreement overleaf.***
**** Only once formal invoices will have been issued and settled, the LoA will be considered as issued and effective.***
** LoA applicants will be informed by separate email or via SIEF communication if the CSR and guidance on safe use will be prepared jointly and also **submitted jointly**, or rather whether they will be prepared jointly but will have to be **submitted individually**. In the latter case, LoA applicants will receive the CSR and guidance on safe use via a Iuclid so-called "export file" and must then insert it themselves into their individual REACH registration.*

Substance:

CAS 68425-17-2 Syrups, hydrolyzed starch, hydrogenated; Description: A complex combination obtained by the catalytic hydrogenation of hydrolyzed starch syrups. It consists primarily of Sorbitol, Maltitol, Maltotriitol, and hydrogenated oligo and polysaccharides

Current Prices LoA:

☐ Below 10 tons or intermediate: EUR 45.036,- (excl. VAT)
☐ 10 - 100 tons: EUR 45.036,- (excl. VAT)
☐ 100 - 1000 tons: EUR 45.036,- (excl. VAT)
☐ Above 1000 tons: EUR 45.036,- (excl. VAT)

Please fill in applicable joint submission category. Any change in category (higher tonnage or change from intermediate to full substance registration) will require notification to Jones Day to adapt price.

Restrictions (optional):

a. ☐ 'Opt-out' pursuant to Article 11 (3) for the following mandatory joint parts.
☐ Article 10 (a)
☐ Article 10 (a) (iv),
☐ Article 10 (a) (vi),
☐ Article 10 (a) (vii),
☐ Article 10 (a) (ix)

Identification

Company: .....

.....

REACH-IT UUID Number: .....

Company reference name or number (optional): .....

VAT number: .....

If you do not fill out a VAT number, you will be charged 21%.

Address: .....

.....

Postal Code: ..... City: ..... Country: .....

Please give full details of person authorized to make the application:

Mr ☐ Ms ☐ Dr ☐

Last Name: ..... First Name: .....

Phone Number: ..... Fax Number: .....

E-mail address: .....

Please give full company details for all affiliates to be covered by this Letter of Access:
Example: The Miracle Chemicals Co. Ltd; 95130 Rome, 25 Nano Boulevard, Belgium

Affiliates: .....

.....

.....

.....

.....

.....

.....

.....

Registration

In his registration, the Applicant acts:

a. ☐ for **himself**

b. ☐ as **Only Representative** pursuant to Article 8 REACH for the following non-EU manufacturer;
Please give full contact details of **non-EU legal entity** represented by Only Representative
If you act on behalf of several non-EU legal entities that are not related to each other, please fill in new application form for each of your principals.

Company: .....

.....

Address: .....

.....

Postal Code: ..... City: ..... Country: .....

Mr ☐ Ms ☐ Dr ☐

Last Name: ..... First Name: .....

Phone Number: ..... Fax Number: .....

E-mail address: .....

c. ☐ as **Third Party Representative** pursuant to Article 4 REACH.

Do you want to disclose the name of the party you represent?
a. ☐ Yes
b. ☐ No

Company Name: .....

.....

REACH-IT UUID Number: .....

Address: .....

.....

Postal Code: ..... City: ..... Country: .....

Mr ☐ Ms ☐ Dr ☐

Last Name: ..... First Name: .....

Phone Number: ..... Fax Number: .....

E-mail address: .....

Applicable Joint Submission:

Is the **company to be invoiced** the same as the legal entity registering under REACH?

a. ☐ Yes

b. ☐ No

If no, please give full company details of legal entity to be invoiced:

Company: .....

VAT number: .....

If you do not fill in a VAT number, you will be charged 21%.

Address: .....

.....

Postal Code: ..... City: ..... Country: .....

General Terms and Conditions:

1. The right of referral only gives access to the Joint Registration Dossier of the substance for the registration as specified above.
2. The right of referral is solely granted in favor of the Applicant (and, only where applicable, the Affiliates listed herein), and is not transferable to any other entity or person.
3. Unless otherwise specified below at 6., the Applicant is not authorized to receive any copies of the Joint Registration Dossier nor is the Applicant authorized to inspect or view the Joint Registration Dossier or any related specific document in whole or in part, outside the general inspection period granted by the Consortium and outside the conditions set out in the SIEF Agreement.
4. This Letter of Access shall in no event be construed as granting the Applicant any property rights whatsoever in the Joint Registration Dossier.
5. Nothing in this letter shall require the Consortium members to file any additional data.
6. In as far as the Joint Registration Dossier may contain a chemical safety report ("CSR") and guidance on safe use, and the Applicant is participating in joint submission for those parts of the dossier, or has otherwise acquired rights to them, those will be made available to the Applicant as needed and may be used by it in as far as needed for purposes of safe handling and elaboration of eSDS and must be filed by it individually if set out in the SIEF Agreement.
7. If the Applicant has chosen to prepare itself the CSR, exposure scenarios and guidance on safe use, but does otherwise fully participate in the Joint Registration Dossier, it shall receive an electronic copy of parts Article 10 (a) (iv), (vi), (vii) and (ix) REACH of the Joint Registration Dossier and shall have the rights to use for this purpose only the (robust) study summaries and other information contained therein as well as to refer to the full study reports on which basis the (robust) study summaries have been developed.
8. In any event and regardless of the rights and restrictions set forth above, the Applicant shall always receive a list of uses which are covered by the CSR, the proposed classification and labeling as well as the PNECs and DNELs where available.

This Letter of Access does not create any rights for third parties or any liability towards third parties in relation to the data for which access is granted.

This letter of access is issued by the above Lead Registrant or Consortium Members and they have prepared the respective registration dossier(s). No attorney-client relationship with Jones Day is created by signing this LoA application / change form / the SIEF / Cooperation / Joint Submission Agreement or payment of the LoA (proforma) invoice.

Applicant's certifications and undertakings:

1. The Applicant hereby declares that it is aware of, agrees and complies with the provisions of the SIEF Agreement issued by the Lead Registrant, which shall apply in its entirety in addition to the provisions set out hereunder.
2. In case the Applicant has applied for an intermediate LoA only, the Applicant hereby declares that it is aware that registration as an intermediate pursuant to Articles 17 and 18 REACH is conditional upon fulfillment of the conditions set out there under.
3. The Applicant declares that it has wired the Letter of Access Pre-payment fee to the following bank account within 30 calendar days of signature of this Letter of Access. The joint token will be issued after receipt of the pre-payment. The invoice for the Letter of Access / Joint Submission will be issued after pre-payment has been received, but at the latest at the end of the applicable year of registration (end 2010, end 2013, end of 2018, as the case may be).
4. If Applicant chooses not to disclose the Third Party represented, Jones Day reserves the right to appoint a neutral party that is entitled to audit the accuracy of the Third Party Representative's submission whilst guaranteeing the confidentiality of the Third Party. The Third Party Representative hereby agrees to such third party audit.

I have read and I agree with the legal Terms of the Agreement.

Signature of LoA applicant: ……..

Name: ……..

Date: ……..

* * *

REACH: SIEF Communications
Syrups, hydrolyzed starch, hydrogenated
CAS 68425-17-2

- Updated October 2022 -

SIEF Communications (*most recent on top*):

5th SIEF Communication dated October 12, 2022 (4 page)

4th SIEF Communication dated February 10, 2022 (1 page)

3rd SIEF Communication dated June 18, 2021 (47 pages)

2nd SIEF Communication dated May 25, 2021 (2 pages)

1st SIEF Communication dated November 2, 2010 (including SIEF Agreement) (38 pages)

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(10)Member of the Ukrainian Bar

DIRECT NUMBER: 26451460
E-MAIL: USCHLIESSNER@JONESDAY.COM

BY ELECTRONIC MAIL

October 12, 2022 567713-600001

TO WHOM IT MAY CONCERN

Re: REACH: 5th SIEF Communication CAS 68425-17-2 (EC 270-337-8) – Syrups, hydrolyzed starch, hydrogenated.

Dear SIEF Members and Joint Registrants and Interested Parties,

On behalf of Roquette SA (Lead Registrant) and Sorbitol and Maltitol Joint REACH Registration Group (SMJRRG), please find attached:

1. New LoA price calculations, applicable as of October 1, 2022 (end of 12 years data protection period); most recent LoA price calculation preceding October 1, 2022 for reference; and

2. Amendments to the SIEF Agreement, applicable as of today.

Thank you for your attention. For any information on purchasing a Letter of Access, please visit our website https://jonesdayreach.com/substances/ or contact us at ReachTeam@jonesday.com.

Kind regards,

Ursula Schliessner

SMJRRG : LoA calculation (9 SIEF Members) - As of 1st October 2022

October 1, 2022

	TOTAL	Above 1000 tons	100-1000 tons	10-100 tons	Intermediate / 1-10 tons
2010 Budget excluding study costs	€ 173.505	19278,33	19278,33	19278,33	19278,33
2011 Budget	€ 23.500	2611,11	2611,11	2611,11	2611,11
2013 Budget	€ 4.000	444,44	444,44	444,44	444,44
2018 Budget	€ 4.000	444,44	444,44	444,44	444,44
2019 Budget	€ 17.000	1888,89	1888,89	1888,89	1888,89
2020 Budget	€ 10.000	1111,11	1111,11	1111,11	1111,11
2021 Budget	€ 20.000	2222,22	2222,22	2222,22	2222,22
2022 Budget	€ 19.000	2111,11	2111,11	2111,11	2111,11
2023 Budget	€ 29.000	3222,22	3222,22	3222,22	3222,22
2024 Budget	€ 29.000	3222,22	3222,22	3222,22	3222,22
Study Costs - WGS (As of 1st October 2022)	€ -	0,00	0,00	0,00	0,00
Study Costs - Towa/Mitsubishi (As of 1st October 2022)	€ -	0,00	0,00	0,00	0,00
Study Costs - Internal (As of 1st October 2022)	€ -	0,00	0,00	0,00	0,00
Expenses MLA	€ 650	72,22	72,22	72,22	72,22
Expenses Intertek	€ 612	68,00	68,00	68,00	68,00
TOTAL	**€ 330.267**	**€ 36.696**	**€ 36.696**	**€ 36.696**	**€ 36.696**
Admin cost 20% on everything except Study Costs		€ 7.339	€ 7.339	€ 7.339	€ 7.339
Admin cost 15% on Study Costs		€ -	€ -	€ -	€ -
TOTAL WITH ADMIN COST		**€ 44.036**	**€ 44.036**	**€ 44.036**	**€ 44.036**
Handling Fee		€ 1.000	€ 1.000	€ 1.000	€ 1.000
TOTAL LOA PRICE		**€ 45.036**	**€ 45.036**	**€ 45.036**	**€ 45.036**

SMJRRG : LoA calculation (9 SIEF Members)

Version of 15/09/2022 - correction

	TOTAL	Above 1000 tons	100-1000 tons	10-100 tons	Intermediate / 1-10 tons
2010 Budget excluding study costs	€ 173.505	€ 19.278	€ 19.278	€ 19.278	€ 19.278
2011 Budget	€ 23.500	€ 2.611	€ 2.611	€ 2.611	€ 2.611
2013 Budget	€ 4.000	€ 444	€ 444	€ 444	€ 444
2018 Budget	€ 4.000	€ 444	€ 444	€ 444	€ 444
2019 Budget	€ 17.000	€ 1.889	€ 1.889	€ 1.889	€ 1.889
2020 Budget	€ 10.000	€ 1.111	€ 1.111	€ 1.111	€ 1.111
2021 Budget	€ 20.000	€ 2.222	€ 2.222	€ 2.222	€ 2.222
2022 Budget	€ 19.000	€ 2.111	€ 2.111	€ 2.111	€ 2.111
2023 Budget	€ 29.000	€ 3.222	€ 3.222	€ 3.222	€ 3.222
2024 Budget	€ 29.000	€ 3.222	€ 3.222	€ 3.222	€ 3.222
Study Costs - WGS	€ 8.539	€ 949	€ 949	€ 949	€ 949
Study Costs - Towa/Mitsubishi *	€ 19.205	€ 2.134	€ 2.134	€ 2.134	€ 2.134
Study Costs - Internal	€ 296.147	€ 59.229	€ 20.779	€ 6.213	€ 325
Expenses MLA	€ 650	€ 72	€ 72	€ 72	€ 72
Expenses Intertek	€ 612	€ 68	€ 68	€ 68	€ 68
TOTAL	**€ 654.158**	**€ 99.008**	**€ 60.558**	**€ 45.992**	**€ 40.104**
Admin cost 20% on everything except Study Costs		€ 7.339	€ 7.339	€ 7.339	€ 7.339
Admin cost 15% on Study Costs		€ 9.347	€ 3.579	€ 1.394	€ 511
TOTAL WITH ADMIN COST		**€ 115.695**	**€ 71.477**	**€ 54.726**	**€ 47.954**
Handling Fee		€ 1.000	€ 1.000	€ 1.000	€ 1.000
TOTAL LOA PRICE		**€ 116.695**	**€ 72.477**	**€ 55.726**	**€ 48.954**

Notes

* The Towa/Mitsubishi licence fee is marked up to take 4 SIEF members into account because reduction on price for co-owner/license had been granted to one SMJRRG membe

Amendment of SMJRRG SIEF Agreement
October 3, 2022

The SIEF and Joint Submission Agreement is amended as follows with immediate effect from the date of electronic submission to the joint registrants:

(1) **Section 2. (Scope) (b).** At the end of the sentence, the following language is inserted *"and/or concern the registration or use of the substance. This shall include, among others, dossier evaluation, substance evaluation, classification pursuant to Regulation 1272/2008 as amended, risk management options analyses and REACH restrictions."*

(2) **Section 4. (Cost Sharing) (d).** At the end of the sentence, the following language is inserted. *"This shall include the activities to defend the registration and use of the substance mentioned in Section 2.(b)."*

(3) **Section 4. (Cost Sharing) (f).** At the end of the paragraph, the words *"on June 1, 2022"* shall be replaced by *"once the joint registration ends"*.

(4) **Section 5. (Miscellaneous) (c)**. At the end of the sentence, the following language is added *"and any and all applicable trade sanctions laws."*

(5) **Section 5. (Miscellaneous) (f).** (f) shall be replaced as follows: *"Duration and Termination – This SIEF Agreement shall be in force as long as there is a valid joint registration of the Substance. The provisions under 5.(d), (e) and (h) shall survive its term indefinitely, except that the confidentiality obligations in relation to studies submitted to ECHA shall survive for twelve years from the date of their submission.*
The Lead Registrant has the right to terminate its function as Lead Registrant with one month prior written notice (electronic communication shall suffice) to the other joint registrants."

* * *

JONES DAY

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BY ELECTRONIC MAIL

February 10, 2022 567713-600001

TO WHOM IT MAY CONCERN

Re: REACH: 4th SIEF Communication CAS 68425-17-2 (EC 270-337-8) - Syrups, hydrolyzed starch, hydrogenated.

Dear SIEF Members and Joint Registrants,

On behalf of Roquette SA (Lead Registrant) and Sorbitol and Maltitol Joint REACH Registration Group (SMJRRG) and following-up on our SIEF communication of June 18, 2021, we wish to inform you that, after fixing further small issues, the registration dossier update was recently submitted to ECHA and has successfully passed the manual completeness check (February 2022).

If a Letter of Access licensee wishes to receive an updated IUCLID6 and/or CSR, please contact us at ReachTeam@jonesday.com.

Thank you for your attention. For any information on purchasing a Letter of Access, please visit our website https://jonesdayreach.com/substances/.

Kind regards,

Ursula Schliessner

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BY ELECTRONIC MAIL

June 18, 2021 567713-600001

TO WHOM IT MAY CONCERN

Re: REACH: 3rd SIEF Communication CAS 68425-17-2 Syrups, hydrolyzed starch, hydrogenated; Description: A complex combination obtained by the catalytic hydrogenation of hydrolyzed starch syrups. It consists primarily of Sorbitol, Maltitol, Maltotriitol, and hydrogenated oligo and polysaccharides; Registration Dossier will be amended.

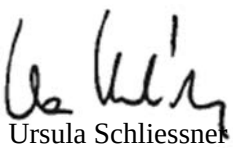
Dear SIEF Members and Joint Registrants,

On behalf of Roquette SA (Lead Registrant) and Sorbitol and Maltitol Joint REACH Registration Group (SMJRRG), we wish to inform you that the SMJRRG registration group has reviewed the **list of uses** and will proceed to an update. Moreover, SMJRRG will proceed to an update of the **substance description**. In the ***attached*** IUCLID6 template, the changes are highlighted in yellow. You may want to take this into account for your next update of the individual part of your registration dossier.

If you have any question or concern about the above matters, we ask that you raise it with us by Friday, **July 2, 2021**. The registration dossier will be updated with ECHA towards the end of August 2021.

Thank you for your attention. For any information on purchasing a Letter of Access, please visit our website at https://jonesdayreach.com/.

Kind regards,



Ursula Schliessner

Annex: IUCLID6 template

Name: Hydrogenated glucose syrups_Update2021 / Syrups, hydrolyzed starch, hydrogenated / 68425-17-2

Legal entity owner: [redacted]

Printing date: 2021-06-10

Summary of uses as discussed on 10.6.2021 in SMJRRG Meeting for final approval

Changes versus previous version (file HydrogenatedGlucoseSyrups_Identity&Uses_20210525_d88213ae-e6be-4838-8b86-df19aa8b9a37_Highlights.pdf) are highlighted yellow.

Table of Contents

Hydrogenated glucose syrups_Update2021

CORE

General information

Composition

FLEXIBLE_RECORD: Syrups, hydrolyzed starch, hydrogenated

UUID:	[redacted]
Dossier UUID:	
Author:	
Date:	
Remarks:	

General Information

Name
Syrups, hydrolyzed starch, hydrogenated

Type of composition
boundary composition of the substance

State / form
liquid

Description
UVCB substance
Methods of manufacture of substance: Catalytic hydrogenation of hydrolyzed starch syrups. It co nsists primarily of sorbitol, maltitol, maltotriitol and hydrogenated oligo and polysaccharides.

Degree of purity

100	% (w/w)

Constituents

Reference substance
D-glucitol / D-glucitol / 50-70-4 / 200-061-5

EC number	EC name
200-061-5	EC Inventory

CAS number	CAS name
50-70-4	D-glucitol

IUPAC name

D-glucitol

Concentration range

>=	0	<= 80	% (w/w)

Reference substance

4-O-a-D-glucopyranosyl-D-glucitol / 4-O-alpha-D-glucopyranosyl-D-glucitol / 585-88-6 / 209-567-0

EC number	EC name
209-567-0	EC Inventory
CAS number	**CAS name**
585-88-6	D-Glucitol, 4-O-.alpha.-D-glucopyranosyl-

IUPAC name

4-O-alpha-D-glucopyranosyl-D-glucitol

Concentration range

>=	0	<= 80	% (w/w)

Reference substance

O-a-D-glucopyranosyl-(1¿4)-O-a-D-glucopyranosyl-(1¿4)-D-glucitol / hexopyranosyl-(1->4)hexopyranosyl-(1->1)hexitol / 32860-62-1 / 251-265-6

EC number	EC name
251-265-6	EC Inventory
CAS number	**CAS name**
32860-62-1	o-alpha-d-glucopyranosyl-(1->4)-o-alpha-d-glucopyranosyl-(1->4)-d-glucitol

IUPAC name

hexopyranosyl-(1->4)hexopyranosyl-(1->1)hexitol

Concentration range

>=	0	<= 80	% (w/w)

Reference substance

Syrups, hydrolyzed starch, hydrogenated, tetramers and higher oligomers / Syrups, hydrolyzed starch, hydrogenated, tetramers and higher oligomers

EC number	EC name
CAS number	**CAS name**

IUPAC name

Syrups, hydrolyzed starch, hydrogenated, tetramers and higher oligomers

Concentration range

>= 0	<= 80	% (w/w)

Reference substance
water / water / 7732-18-5 / 231-791-2

EC number	**EC name**
231-791-2	EC Inventory
CAS number	**CAS name**
7732-18-5	
IUPAC name	
water	

Concentration range

>= 10	<= 31	% (w/w)

Manufacture, use and exposure

Use and exposure information

Manufacture

FLEXIBLE_RECORD: Catalytic hydrogenation of hydrolyzed starches syrups.

UUID:	[redacted]
Dossier UUID:	
Author:	
Date:	
Remarks:	

Manufacture

Registration/ Notification status for the use
use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant

Manufacture number
1

Manufacture name
Catalytic hydrogenation of hydrolyzed starches syrups.

Further description of manufacturing process

Catalytic hydrogenation of hydrolyzed starches syrups.
It consists primarily of sorbitol, maltitol, maltotriitol and hydrogenated oligo and polysaccharides.

Contributing activity / technique for the environment

Environmental release category (ERC)
ERC1: Manufacture of the substance

Contributing activity / technique for workers

Process category (PROC)
PROC28: Manual maintenance (cleaning and repair) of machinery

Process category (PROC)
PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions

Process category (PROC)
PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions

Process category (PROC)
PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions

Process category (PROC) PROC 4: Chemical production where opportunity for exposure arises
Process category (PROC) PROC 7: Industrial spraying
Process category (PROC) PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
Process category (PROC) PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities
Process category (PROC) PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
Process category (PROC) PROC 13: Treatment of articles by dipping and pouring
Process category (PROC) PROC 14: Tabletting, compression, extrusion, pelletisation, granulation
Process category (PROC) PROC 26: Handling of solid inorganic substances at ambient temperature

Total EU tonnage for this use
false

Related assessment
use assessed in a joint CSR

Use takes place under rigorously contained conditions

Rigorously contained system with strict control for manual interventions
false

Rigorously contained system with minimisation of release to the environment
false

Formulation or re-packing

FLEXIBLE_RECORD: Formulation and packaging

UUID:	[redacted]
Dossier UUID:	
Author:	
Date:	
Remarks:	

Formulation

Registration/ Notification status for the use
use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant

Use number
1

Use name
Formulation and packaging

Contributing activity / technique for the environment

Environmental release category (ERC) ERC2: Formulation into mixture
Environmental release category (ERC) ERC3: Formulation into solid matrix

Contributing activity / technique for workers

Process category (PROC) PROC28: Manual maintenance (cleaning and repair) of machinery
Process category (PROC) PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
Process category (PROC) PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
Process category (PROC) PROC 4: Chemical production where opportunity for exposure arises
Process category (PROC) PROC 5: Mixing or blending in batch processes
Process category (PROC) PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
Process category (PROC) PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities

Process category (PROC)
PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)

Process category (PROC)
PROC 14: Tabletting, compression, extrusion, pelletisation, granulation

Process category (PROC)
PROC 15: Use as laboratory reagent

Product category formulated
PC 1: Adhesives, sealants
PC 2: Adsorbents
PC 3: Air care products
PC 4: Anti-freeze and de-icing products
PC 7: Base metals and alloys
PC 8: Biocidal products (e.g. disinfectants, pest control)
PC 9a: Coatings and paints, thinners, paint removes
PC 9b: Fillers, putties, plasters, modelling clay
PC 9c: Finger paints
PC 12: Fertilisers
PC 14: Metal surface treatment products
PC 15: Non-metal-surface treatment products
PC 17: Hydraulic fluids
PC 18: Ink and toners
PC 19: Intermediate
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents
PC 21: Laboratory chemicals
PC 23: Leather treatment products
PC 24: Lubricants, greases, release products
PC 25: Metal working fluids
PC 26: Paper and board treatment products
PC 27: Plant protection products
PC 28: Perfumes, fragrances
PC 29: Pharmaceuticals
PC 30: Photo-chemicals
PC 31: Polishes and wax blends
PC 32: Polymer preparations and compounds
PC 34: Textile dyes, and impregnating products
PC 35: Washing and cleaning products
PC 36: Water softeners
PC 37: Water treatment chemicals
PC 38: Welding and soldering products, flux products
PC 39: Cosmetics, personal care products
PC 40: Extraction agents

Technical function of the substance during formulation
antifreeze agent
chelating agent
lubricating agent
stabilisers
other: sequestring agent, coalescence co-solvent agent, plasticizer, humectant, anti-swelling agent

Substance supplied to that use in form of
as such
in a mixture

Total EU tonnage for this use
false

Limited number of sites for this use
false

Related assessment
use assessed in a joint CSR

Use takes place under rigorously contained conditions

Rigorously contained system with strict control for manual interventions
false

Rigorously contained system with minimisation of release to the environment
false

UUID:	[redacted]
Dossier UUID:	
Author:	
Date:	
Remarks:	

Uses at industrial sites

Registration/ Notification status for the use
use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant

Use number
1

Use name
Manufacture of products and articles

Use as on-site isolated intermediate registered according to REACH Article 17(3)
false

Any precursor use(s)
false

Contributing activity / technique for the environment

Environmental release category (ERC) ERC4: Use of non-reactive processing aid at industrial site (no inclusion into or onto article)
Environmental release category (ERC) ERC5: Use at industrial site leading to inclusion into/onto article
Environmental release category (ERC) ERC6a: Use of intermediate
Environmental release category (ERC) ERC6b: Use of reactive processing aid at industrial site (no inclusion into or onto article)
Environmental release category (ERC) ERC6c: Use of monomer in polymerisation processes at industrial site (inclusion or not into/onto article)
Environmental release category (ERC) ERC6d: Use of reactive process regulators in polymerisation processes at industrial site (inclusion or not into/onto article)
Environmental release category (ERC) ERC7: Use of functional fluid at industrial site

Contributing activity / technique for workers

Process category (PROC) PROC28: Manual maintenance (cleaning and repair) of machinery
Process category (PROC) PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
Process category (PROC) PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
Process category (PROC) PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
Process category (PROC) PROC 4: Chemical production where opportunity for exposure arises
Process category (PROC) PROC 5: Mixing or blending in batch processes
Process category (PROC) PROC 12: Use of blowing agents in manufacture of foam
Process category (PROC) PROC 15: Use as laboratory reagent

Product category used
PC 1: Adhesives, sealants
PC 2: Adsorbents
PC 3: Air care products
PC 4: Anti-freeze and de-icing products
PC 7: Base metals and alloys
PC 8: Biocidal products (e.g. disinfectants, pest control)
PC 9a: Coatings and paints, thinners, paint removes
PC 9b: Fillers, putties, plasters, modelling clay
PC 9c: Finger paints
PC 12: Fertilisers
PC 14: Metal surface treatment products
PC 15: Non-metal-surface treatment products
PC 17: Hydraulic fluids
PC 18: Ink and toners
PC 19: Intermediate
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents
PC 21: Laboratory chemicals
PC 23: Leather treatment products
PC 24: Lubricants, greases, release products
PC 25: Metal working fluids
PC 26: Paper and board treatment products
PC 27: Plant protection products
PC 28: Perfumes, fragrances
PC 30: Photo-chemicals
PC 31: Polishes and wax blends

PC 32: Polymer preparations and compounds
PC 34: Textile dyes, and impregnating products
PC 35: Washing and cleaning products
PC 36: Water softeners
PC 37: Water treatment chemicals
PC 38: Welding and soldering products, flux products
PC 39: Cosmetics, personal care products
PC 40: Extraction agents

Sector of end use
SU 4: Manufacture of food products
SU 5: Manufacture of textiles, leather, fur
SU 6a: Manufacture of wood and wood products
SU 6b: Manufacture of pulp, paper and paper products
SU 7: Printing and reproduction of recorded media
SU 12: Manufacture of plastics products, including compounding and conversion
SU 14: Manufacture of basic metals, including alloys
SU 15: Manufacture of fabricated metal products, except machinery and equipment
SU 19: Building and construction work

Technical function of the substance during use
antifreeze agent
chelating agent
lubricating agent
stabilisers
other: sequestring agent, coalescence co-solvent agent, plasticizer, humectant, anti-swelling agent

Substance supplied to that use in form of
as such
in a mixture

Subsequent service life relevant for this use
yes

Subsequent service life name

CORE / Article service life / Service life as coating/adhesive additive in articles / Hydrogenated glucose syrups_Update2021 / Syrups, hydrolyzed starch, hydrogenated / 68425-17-2

Total EU tonnage for this use
false

Limited number of sites for this use
false

Related assessment
use assessed in a joint CSR

Use takes place under rigorously contained conditions

Rigorously contained system with strict control for manual interventions
false

Rigorously contained system with minimisation of release to the environment
false

FLEXIBLE_RECORD: Intermediate

UUID:	[redacted]
Dossier UUID:	
Author:	
Date:	
Remarks:	

Uses at industrial sites

Registration/ Notification status for the use
use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant

Use number
2

Use name
Intermediate

Use as on-site isolated intermediate registered according to REACH Article 17(3)
false

Any precursor use(s)
false

Contributing activity / technique for the environment

Environmental release category (ERC) ERC6a: Use of intermediate
Environmental release category (ERC) ERC6b: Use of reactive processing aid at industrial site (no inclusion into or onto article)
Environmental release category (ERC) ERC6c: Use of monomer in polymerisation processes at industrial site (inclusion or not into/onto article)
Environmental release category (ERC) ERC6d: Use of reactive process regulators in polymerisation processes at industrial site (inclusion or not into/onto article)
Environmental release category (ERC) ERC7: Use of functional fluid at industrial site

Contributing activity / technique for workers

Process category (PROC) PROC28: Manual maintenance (cleaning and repair) of machinery
Process category (PROC) PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions

Process category (PROC)
PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions

Process category (PROC)
PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions

Process category (PROC)
PROC 4: Chemical production where opportunity for exposure arises

Process category (PROC)
PROC 5: Mixing or blending in batch processes

Process category (PROC)
PROC 15: Use as laboratory reagent

Product category used
PC 2: Adsorbents
PC 3: Air care products
PC 4: Anti-freeze and de-icing products
PC 7: Base metals and alloys
PC 9b: Fillers, putties, plasters, modelling clay
PC 18: Ink and toners
PC 19: Intermediate
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents
PC 21: Laboratory chemicals
PC 27: Plant protection products
PC 30: Photo-chemicals
PC 35: Washing and cleaning products
PC 37: Water treatment chemicals
PC 39: Cosmetics, personal care products

Sector of end use
SU 9: Manufacture of fine chemicals
SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement

Technical function of the substance during use
intermediate (precursor)

Substance supplied to that use in form of
as such
in a mixture

Subsequent service life relevant for this use
no

Total EU tonnage for this use
false

Limited number of sites for this use
false

Related assessment
use assessed in a joint CSR

Use takes place under rigorously contained conditions

Rigorously contained system with strict control for manual interventions
false

Rigorously contained system with minimisation of release to the environment
false

FLEXIBLE_RECORD: Industrial end-use of products and articles

UUID:	[redacted]
Dossier UUID:	
Author:	
Date:	
Remarks:	

Uses at industrial sites

Registration/ Notification status for the use
use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant

Use number
3

Use name
Industrial end-use of products and articles

Use as on-site isolated intermediate registered according to REACH Article 17(3)
false

Any precursor use(s)
false

Contributing activity / technique for the environment

Environmental release category (ERC)
ERC4: Use of non-reactive processing aid at industrial site (no inclusion into or onto article)

Environmental release category (ERC)
ERC5: Use at industrial site leading to inclusion into/onto article

Environmental release category (ERC)
ERC6a: Use of intermediate

Environmental release category (ERC)
ERC6b: Use of reactive processing aid at industrial site (no inclusion into or onto article)

Environmental release category (ERC)
ERC6c: Use of monomer in polymerisation processes at industrial site (inclusion or not into/onto article)

Environmental release category (ERC)
ERC6d: Use of reactive process regulators in polymerisation processes at industrial site (inclusion or not into/onto article)

Environmental release category (ERC)
ERC7: Use of functional fluid at industrial site

Contributing activity / technique for workers

Process category (PROC)
PROC28: Manual maintenance (cleaning and repair) of machinery

Process category (PROC) PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
Process category (PROC) PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
Process category (PROC) PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
Process category (PROC) PROC 4: Chemical production where opportunity for exposure arises
Process category (PROC) PROC 5: Mixing or blending in batch processes
Process category (PROC) PROC 7: Industrial spraying
Process category (PROC) PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
Process category (PROC) PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities
Process category (PROC) PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
Process category (PROC) PROC 10: Roller application or brushing
Process category (PROC) PROC 13: Treatment of articles by dipping and pouring
Process category (PROC) PROC 15: Use as laboratory reagent
Process category (PROC) PROC 17: Lubrication at high energy conditions in metal working operations
Process category (PROC) PROC 19: Hand-mixing with intimate contact and only PPE available.
Process category (PROC) PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles
Process category (PROC) PROC 26: Handling of solid inorganic substances at ambient temperature

Product category used
PC 1: Adhesives, sealants
PC 2: Adsorbents
PC 3: Air care products
PC 4: Anti-freeze and de-icing products
PC 7: Base metals and alloys
PC 8: Biocidal products (e.g. disinfectants, pest control)
PC 9a: Coatings and paints, thinners, paint removes
PC 9b: Fillers, putties, plasters, modelling clay
PC 9c: Finger paints
PC 12: Fertilisers
PC 14: Metal surface treatment products
PC 15: Non-metal-surface treatment products
PC 17: Hydraulic fluids
PC 18: Ink and toners
PC 19: Intermediate
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents
PC 21: Laboratory chemicals
PC 23: Leather treatment products
PC 24: Lubricants, greases, release products
PC 25: Metal working fluids
PC 26: Paper and board treatment products
PC 27: Plant protection products
PC 28: Perfumes, fragrances
PC 29: Pharmaceuticals
PC 30: Photo-chemicals
PC 31: Polishes and wax blends
PC 32: Polymer preparations and compounds
PC 34: Textile dyes, and impregnating products
PC 35: Washing and cleaning products
PC 36: Water softeners
PC 37: Water treatment chemicals
PC 38: Welding and soldering products, flux products
PC 39: Cosmetics, personal care products
PC 40: Extraction agents

Sector of end use
SU 4: Manufacture of food products
SU 5: Manufacture of textiles, leather, fur
SU 6a: Manufacture of wood and wood products
SU 6b: Manufacture of pulp, paper and paper products
SU 7: Printing and reproduction of recorded media
SU 12: Manufacture of plastics products, including compounding and conversion
SU 14: Manufacture of basic metals, including alloys
SU 15: Manufacture of fabricated metal products, except machinery and equipment

Technical function of the substance during use
antifreeze agent
chelating agent
lubricating agent
stabilisers
other: sequestring agent, coalescence co-solvent agent, plasticizer, humectant, anti-swelling agent

Substance supplied to that use in form of
as such
in a mixture

Subsequent service life relevant for this use
yes

Subsequent service life name

CORE / Article service life / Service life as coating/adhesive additive in articles / Hydrogenated glucose syrups_Update2021 / Syrups, hydrolyzed starch, hydrogenated / 68425-17-2

Total EU tonnage for this use
false

Limited number of sites for this use
false

Related assessment
use assessed in a joint CSR

Use takes place under rigorously contained conditions

Rigorously contained system with strict control for manual interventions
false

Rigorously contained system with minimisation of release to the environment
false

Widespread uses by professional workers

FLEXIBLE_RECORD: Professional end-use of products and articles

UUID:	[redacted]
Dossier UUID:	
Author:	
Date:	
Remarks:	

Uses by professional workers

Registration/ Notification status for the use
use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant

Use number
1

Use name
Professional end-use of products and articles

Any precursor use(s)
false

Contributing activity / technique for the environment

Environmental release category (ERC) ERC8f: Widespread use leading to inclusion into/onto article (outdoor)
Environmental release category (ERC) ERC8a: Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)
Environmental release category (ERC) ERC8b: Widespread use of reactive processing aid (no inclusion into or onto article, indoor)
Environmental release category (ERC) ERC8c: Widespread use leading to inclusion into/onto article (indoor)
Environmental release category (ERC) ERC8d: Widespread use of non-reactive processing aid (no inclusion into or onto article, outdoor)

Contributing activity / technique for workers

Process category (PROC) PROC28: Manual maintenance (cleaning and repair) of machinery
Process category (PROC) PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
Process category (PROC) PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions

Process category (PROC) PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions
Process category (PROC) PROC 4: Chemical production where opportunity for exposure arises
Process category (PROC) PROC 5: Mixing or blending in batch processes
Process category (PROC) PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
Process category (PROC) PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities
Process category (PROC) PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
Process category (PROC) PROC 10: Roller application or brushing
Process category (PROC) PROC 11: Non industrial spraying
Process category (PROC) PROC 13: Treatment of articles by dipping and pouring
Process category (PROC) PROC 15: Use as laboratory reagent
Process category (PROC) PROC 17: Lubrication at high energy conditions in metal working operations
Process category (PROC) PROC 19: Hand-mixing with intimate contact and only PPE available.
Process category (PROC) PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles

Product category used
PC 1: Adhesives, sealants
PC 2: Adsorbents
PC 3: Air care products
PC 4: Anti-freeze and de-icing products
PC 7: Base metals and alloys
PC 8: Biocidal products (e.g. disinfectants, pest control)
PC 9a: Coatings and paints, thinners, paint removes
PC 9b: Fillers, putties, plasters, modelling clay
PC 9c: Finger paints
PC 12: Fertilisers

PC 14: Metal surface treatment products
PC 15: Non-metal-surface treatment products
PC 17: Hydraulic fluids
PC 18: Ink and toners
PC 19: Intermediate
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents
PC 21: Laboratory chemicals
PC 23: Leather treatment products
PC 24: Lubricants, greases, release products
PC 25: Metal working fluids
PC 26: Paper and board treatment products
PC 27: Plant protection products
PC 28: Perfumes, fragrances
PC 29: Pharmaceuticals
PC 30: Photo-chemicals
PC 31: Polishes and wax blends
PC 32: Polymer preparations and compounds
PC 34: Textile dyes, and impregnating products
PC 35: Washing and cleaning products
PC 36: Water softeners
PC 37: Water treatment chemicals
PC 38: Welding and soldering products, flux products
PC 39: Cosmetics, personal care products
PC 40: Extraction agents

Sector of end use
SU 4: Manufacture of food products
SU 5: Manufacture of textiles, leather, fur
SU 6a: Manufacture of wood and wood products
SU 6b: Manufacture of pulp, paper and paper products
SU 7: Printing and reproduction of recorded media
SU 12: Manufacture of plastics products, including compounding and conversion
SU 14: Manufacture of basic metals, including alloys
SU 15: Manufacture of fabricated metal products, except machinery and equipment

Technical function of the substance during use
antifreeze agent
chelating agent
lubricating agent
stabilisers
other: sequestring agent, coalescence co-solvent agent, plasticizer, humectant, anti-swelling agent

Substance supplied to that use in form of
as such
in a mixture

Subsequent service life relevant to this use
yes

Subsequent service life name

CORE / Article service life / Service life as coating/adhesive additive in articles / Hydrogenated glucose syrups_Update2021 / Syrups, hydrolyzed starch, hydrogenated / 68425-17-2

Total EU tonnage for this use
false

Related assessment
use assessed in a joint CSR ~~but not a lead's own use~~

Use takes place under rigorously contained conditions

Rigorously contained system with strict control for manual interventions
false

Rigorously contained system with minimisation of release to the environment
false

Consumer uses

FLEXIBLE_RECORD: Consumer end-use of products

UUID:
Dossier UUID:
Author:
Date:
Remarks:

Consumer uses

Registration/ Notification status for the use
use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant

Use number
1

Use name
Consumer end-use of products

Any precursor use(s)
false

Contributing activity / technique for the environment

Environmental release category (ERC) ERC8c: Widespread use leading to inclusion into/onto article (indoor) ERC8f: Widespread use leading to inclusion into/onto article (outdoor)
Environmental release category (ERC) ERC8a: Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)
Environmental release category (ERC) ERC8b: Widespread use of reactive processing aid (no inclusion into or onto article, indoor)

Contributing activity / technique for consumers

Product category (PC) PC 1: Adhesives, sealants
Product category (PC) PC 2: Adsorbents
Product category (PC) PC 3: Air care products
Product category (PC) PC 4: Anti-freeze and de-icing products
Product category (PC) PC 7: Base metals and alloys

Product category (PC) PC 8: Biocidal products (e.g. disinfectants, pest control)
Product category (PC) PC 9a: Coatings and paints, thinners, paint removes
Product category (PC) PC 9b: Fillers, putties, plasters, modelling clay
Product category (PC) PC 9c: Finger paints
Product category (PC) PC 12: Fertilisers
Product category (PC) PC 14: Metal surface treatment products
Product category (PC) PC 15: Non-metal-surface treatment products
Product category (PC) PC 17: Hydraulic fluids
Product category (PC) PC 18: Ink and toners
Product category (PC) PC 19: Intermediate
Product category (PC) PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents
Product category (PC) PC 21: Laboratory chemicals
Product category (PC) PC 23: Leather treatment products
Product category (PC) PC 24: Lubricants, greases, release products
Product category (PC) PC 25: Metal working fluids
Product category (PC) PC 26: Paper and board treatment products
Product category (PC) PC 27: Plant protection products

Product category (PC) PC 28: Perfumes, fragrances
Product category (PC) PC 29: Pharmaceuticals
Product category (PC) PC 30: Photo-chemicals
Product category (PC) PC 31: Polishes and wax blends
Product category (PC) PC 32: Polymer preparations and compounds
Product category (PC) PC 34: Textile dyes, and impregnating products
Product category (PC) PC 35: Washing and cleaning products
Product category (PC) PC 36: Water softeners
Product category (PC) PC 37: Water treatment chemicals
Product category (PC) PC 38: Welding and soldering products, flux products
Product category (PC) PC 39: Cosmetics, personal care products
Product category (PC) PC 40: Extraction agents

Technical function of the substance during use
antifreeze agent
chelating agent
lubricating agent
stabilisers
other: sequestring agent, coalescence co-solvent agent, plasticizer, humectant, anti-swelling agent

Substance supplied to this use in the form of
as such
in a mixture

Subsequent service life relevant to this use
yes

Subsequent service life name

CORE / Article service life / Service life as coating/adhesive additive in articles / Hydrogenated glucose syrups_Update2021 / Syrups, hydrolyzed starch, hydrogenated / 68425-17-2

Total EU tonnage for this use
false

Related assessment
use assessed in a joint CSR

Service life

FLEXIBLE_RECORD: Service life as coating/adhesive additive in articles

UUID:	[redacted]
Dossier UUID:	
Author:	
Date:	
Remarks:	

Service life

Registration/ Notification status for the use
use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant

Service life number
1

Service life name
Use as coating/adhesives additive in articles

Article used by
workers
consumers

Substance intended to be released from article
no

Contributing activity / technique for the environment

Environmental release category (ERC) ERC11b: Widespread use of articles with high or intended release (indoor)
Environmental release category (ERC) ERC10b: Widespread use of articles with high or intended release (outdoor)
Environmental release category (ERC) ERC10a: Widespread use of articles with low release (outdoor)
Environmental release category (ERC) ERC11a: Widespread use of articles with low release (indoor)
Environmental release category (ERC) ERC12c: Use of articles at industrial sites with low release

Contributing activity / technique for consumers

Article category (AC) AC 1: Vehicles
Article category (AC) AC 2: Machinery, mechanical appliances, electrical/electronic articles
Article category (AC) AC 4: Stone, plaster, cement, glass and ceramic articles

Article category (AC) AC 5: Fabrics, textiles and apparel
Article category (AC) AC 6: Leather articles
Article category (AC) AC 7: Metal articles
Article category (AC) AC 8: Paper articles
Article category (AC) AC 10: Rubber articles
Article category (AC) AC 11: Wood articles
Article category (AC) AC 13: Plastic articles

Contributing activity / technique for workers

Process category (PROC) PROC 10: Roller application or brushing
Process category (PROC) PROC 13: Treatment of articles by dipping and pouring
Process category (PROC) PROC 14: Tabletting, compression, extrusion, pelletisation, granulation
Process category (PROC) PROC 15: Use as laboratory reagent
Process category (PROC) PROC 19: Hand-mixing with intimate contact and only PPE available.
Process category (PROC) PROC 21: Low energy manipulation of substances bound in materials and/or articles
Process category (PROC) PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles
Process category (PROC) PROC 25: Other hot work operations with metals
Process category (PROC) PROC28: Manual maintenance (cleaning and repair) of machinery

Technical function of the substance during use
adhesion promotor

binder
brightener
durability agent
elasticiser

Related assessment
use assessed in a joint CSR

Pattern of exposure
occasional

DOMAIN

Substance

SUBSTANCE: Hydrogenated glucose syrups_Update2021

UUID:	[redacted]
Dossier UUID:	
Author:	
Date:	
Remarks:	

Substance name
Hydrogenated glucose syrups_Update2021

Public name
Syrups, hydrolyzed starch, hydrogenated

Legal entity

Contact persons

Person
[redacted]
Last name
[redacted]
First name
[redacted]
Organisation
[redacted]
Department
[redacted]
Title
[redacted]
Phone
[redacted]
Fax
[redacted]
Email
[redacted]
Address 1
[redacted]
Postal code
[redacted]
Town
[redacted]

Country

Identification of substance

Reference substance
Syrups, hydrolyzed starch, hydrogenated / Syrups, hydrolyzed starch, hydrogenated / 68425-17-2 / 270-337-8

EC number	EC name
270-337-8	EC Inventory
CAS number	**CAS name**
68425-17-2	Syrups, hydrolyzed starch, hydrogenated

IUPAC name
Syrups, hydrolyzed starch, hydrogenated

Type of substance

Type of substance
UVCB

Origin
organic

Role in the supply chain

Manufacturer
true

Importer
false

Only representative
false

Downstream user
false

References

REFERENCE_SUBSTANCE: 4-O-a-D-glucopyranosyl-D-glucitol

UUID:	[redacted]
Dossier UUID:	
Author:	
Date:	
Remarks:	

Reference substance name
4-O-a-D-glucopyranosyl-D-glucitol

IUPAC name
4-O-alpha-D-glucopyranosyl-D-glucitol

Inventory

Inventory number

Inventory name
4-O-α-D-glucopyranosyl-D-glucitol

Inventory
EC Inventory

Inventory number
209-567-0

CAS number
585-88-6

Molecular formula
C12H24O11

Description

CAS number
585-88-6

CAS name
D-Glucitol, 4-O-.alpha.-D-glucopyranosyl-

Synonyms

Synonyms

Identity
D-Glucitol, 4-O-.alpha.-D-glucopyranosyl-

Molecular and structural information

Molecular formula
C12H24O11

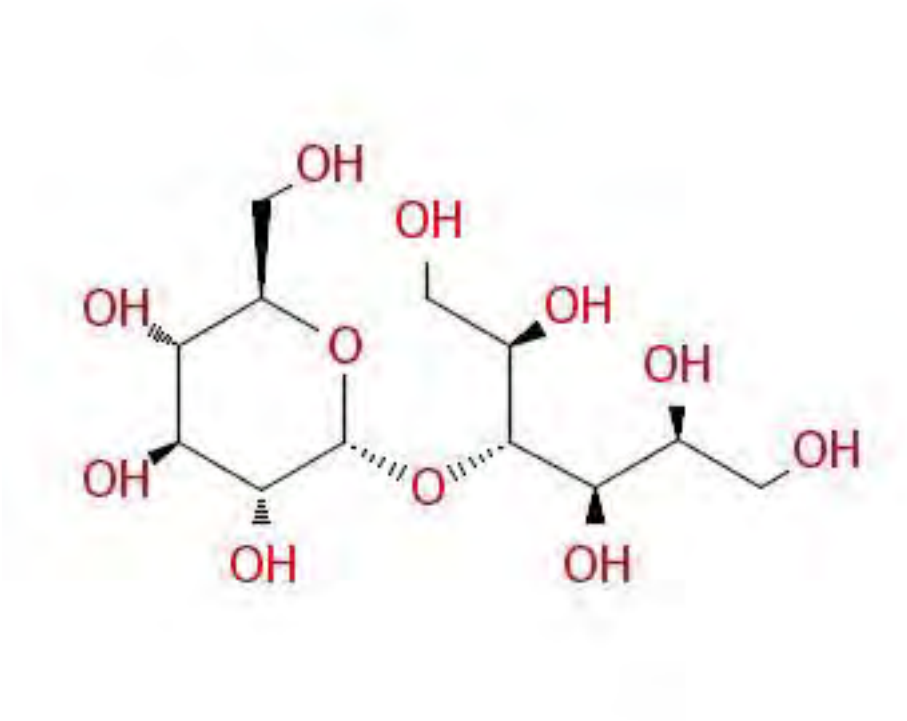
Molecular weight

344.3124

SMILES notation
OC[C@@H](O)[C@@H](O[C@H]1O[C@H](CO)[C@@H](O)[C@H](O)[C@H]1O)[C@H](O)[C@@H](O)CO

InChI
InChI=1/C12H24O11/c13-1-4(16)7(18)11(5(17)2-14)23-12-10(21)9(20)8(19)6(3-15)22-12/h4-21H,1-3H2

Structural formula



CONTACT: [redacted]

UUID:
Dossier UUID:
Author:
Date:
Remarks:

[redacted]

General information

Last name [redacted]

First name [redacted]

Organisation [redacted]

Department [redacted]

Title [redacted]

Phone [redacted]

Fax [redacted]

Email [redacted]

Address 1 [redacted]

Postal code [redacted]

Town [redacted]

Country [redacted]

REFERENCE_SUBSTANCE: D-glucitol

UUID:
Dossier UUID:
Author:
Date:
Remarks:

[redacted]

Reference substance name
D-glucitol

IUPAC name
D-glucitol

Inventory

Inventory number

Inventory name
D-glucitol

Inventory
EC Inventory

Inventory number
200-061-5

CAS number
50-70-4

Molecular formula
C6H14O6

Description

CAS number
50-70-4

CAS name
D-glucitol

Synonyms

Synonyms

Identity
D-Glucitol

Molecular and structural information

Molecular formula
C6H14O6

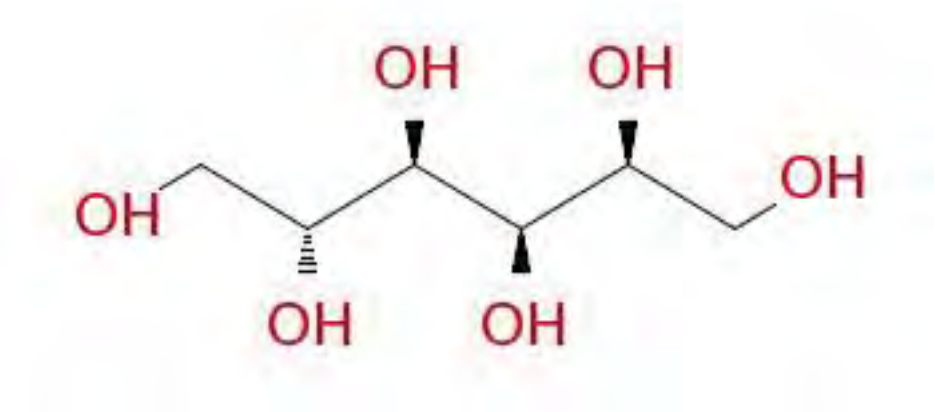
Molecular weight

182.1718

SMILES notation
C(C(C(C(C(CO)O)O)O)O)O

InChI
InChI=1/C6H14O6/c7-1-3(9)5(11)6(12)4(10)2-8/h3-12H,1-2H2

Structural formula



Related substances

Group / category information
DSL Category: Organics

REFERENCE_SUBSTANCE: O-a-D-glucopyranosyl-(1¿4)-O-a-D-glucopyranosyl-(1¿4)-D-glucitol

UUID:	[redacted]
Dossier UUID:	
Author:	
Date:	
Remarks:	

Reference substance name
O-a-D-glucopyranosyl-(1¿4)-O-a-D-glucopyranosyl-(1¿4)-D-glucitol

IUPAC name
hexopyranosyl-(1->4)hexopyranosyl-(1->1)hexitol

Inventory

Inventory number

Inventory name
O-α-D-glucopyranosyl-(1→4)-O-α-D-glucopyranosyl-(1→4)-D-glucitol

Inventory
EC Inventory

Inventory number
251-265-6

CAS number
32860-62-1

Molecular formula
C18H34O16

Description

CAS number
32860-62-1

CAS name
o-alpha-d-glucopyranosyl-(1->4)-o-alpha-d-glucopyranosyl-(1->4)-d-glucitol

Synonyms

Synonyms

Identity
o-alpha-d-glucopyranosyl-(1->4)-o-alpha-d-glucopyranosyl-(1->4)-d-glucitol

Molecular and structural information

Molecular formula
C18H34O16

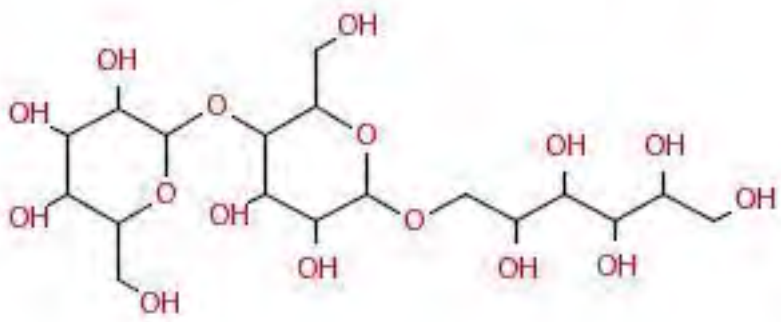
Molecular weight

506.453

SMILES notation
OCC(O)C(O)C(O)C(O)COC1OC(CO)C(OC2OC(CO)C(O)C(O)C2O)C(O)C1O

InChI
InChI=1/C18H34O16/c19-1-5(22)9(24)10(25)6(23)4-31-17-15(30)13(28)16(8(3-21)33-17)34-18-14(29)12(27)11(26)7(2-20)32-18/h5-30H,1-4H2

Structural formula



Related substances

Group / category information
USEPA Category: Neutral Organics

REFERENCE_SUBSTANCE: Syrups, hydrolyzed starch, hydrogenated

UUID:	[redacted]
Dossier UUID:	
Author:	
Date:	
Remarks:	

Reference substance name
Syrups, hydrolyzed starch, hydrogenated

IUPAC name
Syrups, hydrolyzed starch, hydrogenated

Description
A complex combination obtained by the catalytic hydrogenation of hydrolyzed starch syrups, derived from cereal grains such as corn, wheat and sorghum and from roots and tubers such as potatoes and tapioca. It consists primarily of Sorbitol, Maltitol, Maltotriitol and hydrogenated oligo and polysaccharides.

Inventory

Inventory number

Inventory name
Syrups, corn, hydrogenated

Inventory
EC Inventory

Inventory number
270-337-8

CAS number
68425-17-2

Molecular formula

Description

CAS number
68425-17-2

CAS name
Syrups, hydrolyzed starch, hydrogenated

Synonyms

Synonyms

Identity
hydrogenated maltose

Identity maltitol syrup
Identity hydrogenated high maltose-content glucose syrup
Identity hydrogenated glucose syrup (HGS)
Identity dried maltitol syrup
Identity maltitol syrup powder
Identity polyglycitol syrup
Identity [redacted]
Identity [redacted]
Identity [redacted]
Identity Non-crystallising sorbitol solution

Molecular and structural information

Molecular formula
UVCB substance: not applicable

Molecular weight

> 182

SMILES notation
UVCB substance: not applicable

InChI
UVCB substance: not applicable

Remarks
A complex combination obtained by the catalytic hydrogenation of hydrolyzed starch syrups. It consis ts primarily of Sorbitol, Maltitol, Maltotriitol and hydrogenated oligo and polysaccharides.
Note that the Chemical abstracts services changed the CAS name and has removed the botanical origin.

Related substances

Identifier
CAS name

Identity
[redacted]

Relation
other:

Identifier
CAS number

Identity
9053-46-7

Relation
other:

Identifier
CAS name

Identity
Non-crystallising sorbitol solution

Relation
other: Other identifier for the substance Syrups, hydrolyzed starch, hydrogenated

Identifier
CAS number

Identity
1259528-21-6

Relation
other: Other identifier for the substance Syrups, hydrolyzed starch, hydrogenated

REFERENCE_SUBSTANCE: Syrups, hydrolyzed starch, hydrogenated, tetramers and higher oligomers

UUID:	[redacted]
Dossier UUID:	
Author:	
Date:	2010-07-23T10:00:20.000-05:00
Remarks:	

Reference substance name
Syrups, hydrolyzed starch, hydrogenated, tetramers and higher oligomers

IUPAC name
Syrups, hydrolyzed starch, hydrogenated, tetramers and higher oligomers

Description
High molecular weight polyols obtained by hydrolyzed starch, hydrogenated

Inventory

No inventory information available - Justification
not yet assigned

Molecular and structural information

Molecular formula
UVCB substance: not applicable

SMILES notation
UVCB substance: not applicable

InChI
UVCB substance: not applicable

Remarks
High molecular weight polyols obtained by hydrolyzed starch, hydrogenated

REFERENCE_SUBSTANCE: water

UUID:	[redacted]
Dossier UUID:	
Author:	
Date:	2021-04-23T12:37:36.195-05:00
Remarks:	

Reference substance name
water

IUPAC name
water

Inventory

Inventory number

Inventory name
water

Inventory
EC Inventory

Inventory number
231-791-2

CAS number
7732-18-5

Molecular formula
H2O

Description

CAS number
7732-18-5

Synonyms

Synonyms

Identity
Water

Identity
Water

Molecular and structural information

Molecular formula
H2O

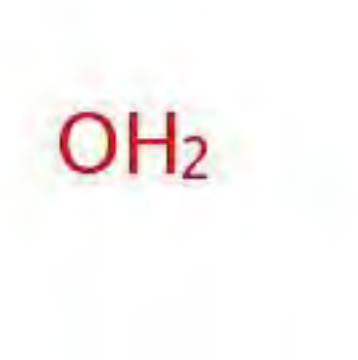
Molecular weight

ca. 18.0153

SMILES notation
O

InChI
InChI=1/H2O/h1H2

Structural formula



Related substances

Group / category information
DSL Category: Inorganics

JONES DAY
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MICHÈLE GRÉGOIRE(6)
Avocat à la Cour de cassation
Advocaat bij het Hof van Cassatie
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CHANTAL BIERNAUX
CHARLOTTE BREUVART(2)
FERDINAND BRUGHMANS
SÉBASTIEN CHAMPAGNE
SERGE CLERCKX
THOMAS DE MUYNCK(3)
LAURENT DE MUYTER
CHARLES de NAVACELLE(2)(3)
YVAN DESMEDT
MATTHIEU DUPLAT
KAARLI H. EICHHORN(10)
VANESSA FONCKE
JÖRG HLADJK(9)
EVA MONARD
URSULA SCHLIESSNER(5)
CRISTIANA SPONTONI(1)
MARIO TODINO(7)
JONAS VAN DEN BOSSCHE
ALEXANDRE VERHEYDEN(3)
PHILIPP WERNER(8)

PHILIPPE LACONTE
HOWARD M LIEBMAN(4)
GEOFFROY VAN DE WALLE
PAUL VAN HOOGHTEN

Members of the Brussels Bar
(1)Member of the Rome Bar
(2)Member of the Paris Bar
(3)Member of the New York Bar
(4)Member of the District of Columbia Bar
(5)Member of the Düsseldorf Bar
(6)Admitted to the Paris Bar
(7)Member of the Naples Bar
(8)Member of the Berlin Bar
(9)Member of the Frankfurt am Main Bar
(10)Member of the Swedish Bar

DIRECT NUMBER: +32 (0)2 645 14 60
USCHLIESSNER@JONESDAY.COM

BY ELECTRONIC MAIL

May 25, 2021

567713-600001

TO WHOM IT MAY CONCERN

Re: REACH: 2nd SIEF Communication CAS 68425-17-2 Syrups, hydrolyzed starch, hydrogenated; Description: A complex combination obtained by the catalytic hydrogenation of hydrolyzed starch syrups. It consists primarily of Sorbitol, Maltitol, Maltotriitol, and hydrogenated oligo and polysaccharides; Letter of Access price will be amended

Dear SIEF Members and Joint Registrants,

On behalf of Roquette SA (Lead Registrant) and Sorbitol and Maltitol Joint REACH Registration Group, set out below and attached are the amended letter of access prices as of March 2021.

- Below 10 tons or intermediate: EUR 41,221 (excl. VAT)
- 10 - 100 tons: EUR 49,422 (excl. VAT)
- 100 - 1000 tons: EUR 64,744 (excl. VAT)
- Above 1000 tons: EUR 108,961 (excl. VAT)

Thank you for your attention. For any information on purchasing a Letter of Access, please visit our website at https://jonesdayreach.com/.

Kind regards,

Ursula Schliessner

Annex: SMJRRG LoA calculation (9 SIEF members)

ANNEX

SMJRRG : LoA calculation (9 SIEF Members)

	TOTAL	Above 1000 tons	100-1000 tons	10-100 tons	Intermediate / 1-10 tons
2010 Budget excluding study costs	€ 173.505	€ 19.278	€ 19.278	€ 19.278	€ 19.278
2011 Budget	€ 23.500	€ 2.611	€ 2.611	€ 2.611	€ 2.611
2013 Budget	€ 4.000	€ 444	€ 444	€ 444	€ 444
2018 Budget	€ 4.000	€ 444	€ 444	€ 444	€ 444
2019 Budget	€ 17.000	€ 1.889	€ 1.889	€ 1.889	€ 1.889
2020 Budget	€ 10.000	€ 1.111	€ 1.111	€ 1.111	€ 1.111
2021 Budget	€ 20.000	€ 2.222	€ 2.222	€ 2.222	€ 2.222
2022 Budget	€ 19.000	€ 2.111	€ 2.111	€ 2.111	€ 2.111
Study Costs - WGS	€ 8.539	€ 949	€ 949	€ 949	€ 949
Study Costs - Towa/Mitsubishi *	€ 19.205	€ 2.134	€ 2.134	€ 2.134	€ 2.134
Study Costs - Internal	€ 296.147	€ 59.229	€ 20.779	€ 7.456	€ 325
Expenses MLA	€ 650	€ 72	€ 72	€ 72	€ 72
Expenses Intertek	€ 612	€ 68	€ 68	€ 68	€ 68
TOTAL	**€ 596.158**	**€ 92.564**	**€ 54.114**	**€ 40.791**	**€ 33.659**
Admin cost 20% on everything except Study Costs		€ 6.050	€ 6.050	€ 6.050	€ 6.050
Admin cost 15% on Study Costs		€ 9.347	€ 3.579	€ 1.581	€ 511
TOTAL WITH ADMIN COST		**€ 107.961**	**€ 63.744**	**€ 48.422**	**€ 40.221**
Handling Fee		€ 1.000	€ 1.000	€ 1.000	€ 1.000
TOTAL LOA PRICE		**€ 108.961**	**€ 64.744**	**€ 49.422**	**€ 41.221**

Notes

* The Towa/Mitsubishi licence fee is marked up to take 4 SIEF members into account because reduction on price for co-owner/license had been granted to one SMJRRG member.

09/03/2021

Albany
Atlanta
Brussels
Denver
Los Angeles
New York
Philadelphia
San Diego
San Francisco
Washington, D.C.

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Attorneys at Law

2, Avenue de Tervueren
1040 Brussels, Belgium
Telephone: (32-2) 278-1211 ■ Telefax: (32-2) 278-1200
www.mckennalong.com

Flavia Distefano [1]
Ursula Schliessner [2]
Richard R. Willis [3]
Nora Wouters [4]
[1] Member of the Rome Bar
[2] Member of the Düsseldorf Bar
[3] Member of the Georgia Bar
[4] Advocaat-Avocat - Member of the Brussels Bar

URSULA SCHLIESSNER
(32-2) 278-1224

EMAIL ADDRESS
uschliessner@mckennalong.com

November 2, 2010

BY ELECTRONIC MAIL

TO WHOM IT MAY CONCERN
- SIEF Communication on behalf of Roquette SA (Lead Registrant) and Sorbitol and Maltitol Joint REACH Registration Group -

Re: REACH: SIEF Communication CAS 68425-17-2 Syrups, hydrolyzed starch, hydrogenated; Description: A complex combination obtained by the catalytic hydrogenation of hydrolyzed starch syrups. It consists primarily of Sorbitol, Maltitol, Maltotriitol, and hydrogenated oligo and polysaccharides

Dear SIEF Member:

Pursuant to our last SIEF communication of May 28, 2010, we are pleased to report that the REACH registration dossier has been submitted to ECHA and has passed the technical completeness check and Business Rules.

Set out below and overleaf is critical information for your perusal as well as about the next steps to be taken by SIEF members.

1) Data

No new data was communicated to the Consortium pursuant to our SIEF requests. The Consortium has therefore used and chosen from the data previously collected. We shall assume that you agree with the Consortium's selection of data for use in the joint registration dossiers per Article 11 (1) and 29 (3) REACH.

2) Joint Registration Dossier - Inspection Period

The final joint registration dossier will be made available for inspection at the offices of McKenna Long & Aldridge LLP during office hours between **November 8 and November 22, 2010, upon appointment taken at least 48 hours in advance.**

3) Classification & Labeling

Based on the data available and reviewed, the substance has not been classified under either Directive 67/548 or the CLP Regulation. However, individual SIEF members are responsible for their individual substances and we therefore ask you to verify this for your specific substance.

4) DNEL & PNECs

The DNELs & PNECs derived are set out in **Appendix 1.**

5) Chemical Safety Report

The CSR was prepared jointly by the SMJRRG and has been submitted jointly in the Lead Registrant's dossier (see for submission options ECHA Data Submission Manual http://echa.europa.eu/doc/reachit/dsm_19_how_joint_csr_en.pdf). However, as regards individual uses, please see 6) below. A copy of the CSR will be provided to interested SIEF members upon request simultaneously with the joint submission name and token.

6) Uses and Guidance on safe use

For PROCs, SUs and ERCs covered in the CSR, please refer to **Appendix 2.** Individual uses and article categories (ACs, PCs) are not covered in the joint CSR as these were considered confidential. They must be added by each registrant in Section 3.5. Iuclid and potentially to the CSR. Guidance on safe use has been prepared and submitted jointly and is available to LoA applicants upon request once they have completed 9) below.

7) Substance ID

Substance sameness was agreed earlier in the SIEF. The substance identity used is attached as **Appendix 3**.

8) SIEF Agreement

We ask that those SIEF members who wish to participate in joint registration sign and return to us by e-mail the signature page of the SIEF Agreement distributed earlier, again attached hereto (**Appendix 4**).

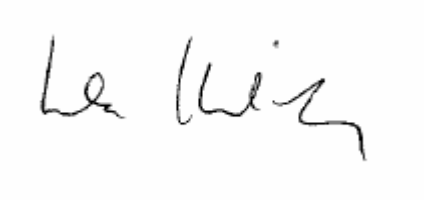
9) Participation in Joint Submission - Letters of Access

We would further kindly ask those SIEF members who wish to participate in joint submission to fill in a letter of access (LoA) application at www.mlalaw.eu. An on-line tool will guide you through the procedure and payment requirements. For your information, the price for an LoA (1,000 tons) will be €153,599 (excl. VAT where applicable). This price includes affiliated legal entities of the LoA applicant. It also includes the CSR. For a detailed calculation of the LoA price and studies used, please refer to **Appendix 5**. Once your LoA application has been duly accepted and payment has been made, you shall automatically receive the joint submission token to file the individual parts of your registration dossiers.

Participation in joint submission is conditional upon completing the procedure and obtaining an LoA at www.mlalaw.eu.

Thank you very much for your attention.

Kind regards,



Ursula Schliessner
Partner
McKenna Long & Aldridge LLP

Appendix 1 - DNELs and PNECs

Table 21. DN(M)ELs for workers

Exposure pattern	Route	Descriptor	DNEL / DMEL	(Corrected) Dose descriptor *)	Most sensitive endpoint	Justification
Acute - systemic effects	Dermal					
Acute - systemic effects	Inhalation					
Acute - local effects	Dermal					
Acute - local effects	Inhalation					
Long-term - systemic effects	Dermal	DNEL (Derived No Effect Level)	2000 mg/kg bw/day		repeated dose toxicity	
Long-term - systemic effects	Inhalation	DNEL (Derived No Effect Level)	5 mg/m³		repeated dose toxicity	
Long-term - local effects	Dermal					
Long-term - local effects	Inhalation					

**) The (corrected) dose descriptor starting points have been automatically calculated by multiplying the values of the fields "D(N)MEL" and "Assessment factor" provided in the Endpoint summary of IUCLID section 7. Toxicological information. It reflects the value after any corrections, e.g. route-to-route extrapolation. See column "Justification" for the rationale behind such modifications and the use of assessment factors.*

Table 22. DN(M)ELs for the general population

Exposure pattern	Route	Descriptor	DNEL / DMEL	(Corrected) Dose descriptor *)	Most sensitive endpoint	Justification
Acute - systemic effects	Dermal					
Acute - systemic effects	Inhalation					
Acute - systemic effects	Oral					
Acute - local effects	Dermal					
Acute - local effects	Inhalation					
Long-term - systemic effects	Dermal	DNEL (Derived No Effect Level)	2000 mg/kg bw/day		repeated dose toxicity	
Long-term - systemic effects	Inhalation	DNEL (Derived No Effect Level)	0.89 mg/m³	: 1.78 mg/m³ (based on AF of 2)	repeated dose toxicity	
Long-term - systemic effects	Oral	DNEL (Derived No Effect Level)	200 mg/kg bw/day		repeated dose toxicity	
Long-term - local effects	Dermal					
Long-term - local effects	Inhalation					

**) The (corrected) dose descriptor starting points have been automatically calculated by multiplying the values of the fields "D(N)MEL" and "Assessment factor" provided in the Endpoint summary of IUCLID section 7. Toxicological information. It reflects the value after any corrections, e.g. route-to-route extrapolation. See column "Justification" for the rationale behind such modifications and the use of assessment factors.*

7.1.2. Calculation of Predicted No Effect Concentration (PNEC)

7.1.2.1. PNEC water

Table 26. PNEC water

PNEC	Assessment factor	Remarks/Justification
PNEC aqua (freshwater): 0.973 mg/L	1000	Extrapolation method: assessment factor
PNEC aqua (marine water): 0.0973 mg/L	10000	Extrapolation method: assessment factor
PNEC aqua (intermittent releases): 9.73 mg/L	100	Extrapolation method: assessment factor

7.1.2.2. PNEC sediment

Table 27. PNEC sediment

PNEC	Assessment factor	Remarks/Justification
PNEC sediment (freshwater): 3.63 mg/kg sediment dw		Extrapolation method: partition coefficient
PNEC sediment (marine water): 0.363 mg/kg sediment dw		Extrapolation method: partition coefficient

7.2.2. Calculation of Predicted No Effect Concentration (PNEC soil)

Table 28. PNEC soil

PNEC	Assessment factor	Remarks/Justification
PNEC soil: 0.15 mg/kg soil dw		Extrapolation method: partition coefficient

7.4.2. PNEC for sewage treatment plant

Table 29. PNEC sewage treatment plant

Value	Assessment factor	Remarks/Justification
PNEC STP: 66.7 mg/L	10	Extrapolation method: assessment factor

7.5.3. Calculation of PNECoral (secondary poisoning)

Table 30. PNEC oral

PNEC	Assessment factor	Remarks/Justification
No potential for bioaccumulation		The substance has no potential to cause toxic effects and there are no indications that it bioaccumulates in higher organisms. Based on the low bioaccumulation potential and its ready biodegradability secondary poisoning is not regarded as relevant.

PNEC water(freshwater)

		Value		Assessment factor		Remarks/Justification	
PNEC water (freshwater)		0.973 mg/L		1000		Based on the results of short-term toxicity studies with aquatic organisms	

PNEC water (marine water)

	Value	Assessment factor	Remarks/Justification
PNEC water (marine water)	0.0973 mg/L	10000	Based on the results of short-term toxicity studies with aquatic organisms

PNEC water (intermittent release)

	Value	Assessment factor	Remarks/Justification
PNEC water (intermittent release)	9.73 mg/L	100	Based on the results of short-term toxicity studies with aquatic organisms

PNEC Sewage Treatment Plant (STP)

	Value	Assessment factor	Remarks/Justification
PNEC Sewage Treatment Plant (STP)	66.7 mg/L	10	Based on the results of a ready biodegradability test

PNEC sediment (freshwater)

	Value	Assessment factor	Remarks/Justification
PNEC sediment (freshwater)	3.63 mg/kg	Not applicable	Equilibrium partitioning Chemical class for Koc – QSAR: Alcohols Log Kow < -1

PNEC sediment (marine water)

	Value	Assessment factor	Remarks/Justification
PNEC sediment (marine water)	0.363 mg/kg	Not applicable	Equilibrium partitioning. Chemical class for Koc – QSAR: Alcohols Log Kow < -1

PNEC soil

	Value	Assessment factor	Remarks/Justification
PNEC soil	0.15 mg/kg	Not applicable	Equilibrium partitioning Chemical class for Koc – QSAR: Alcohols
			Log Kow: < -1 Water solubility: > 10000 mg/L Vapour pressure: 1210 Pa at 20°C MW: > 182 g/mol

PNEC oral

	Value	Assessment factor	Remarks/Justification
PNEC oral	--	--	Not relevant

Appendix 2 – Uses

2.2. Identified uses

Table 4. Uses by workers in industrial settings

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
	1	Manufacture of products and articles		**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 7: Industrial spraying PROC 10: Roller application or brushing PROC 13: Treatment of articles by dipping and pouring PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 26: Handling of solid inorganic substances at ambient temperature **Market sector by type of chemical product:** PC 0: Other: Confidential, not included in the shared CSR **Environmental release category (ERC):** ERC 1: Manufacture of substances ERC 2: Formulation of preparations ERC 3: Formulation in materials ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles ERC 5: Industrial use resulting in inclusion into or onto a matrix ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates) ERC 6b: Industrial use of reactive processing aids ERC 6c: Industrial use of monomers for manufacture of thermoplastics ERC 6d: Industrial use of process regulators for polymerisation processes in production of resins, rubbers, polymers ERC 7: Industrial use of substances in closed systems ERC 8a: Wide dispersive indoor use of processing aids in open systems ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix ERC 8d: Wide dispersive outdoor use of processing aids in open systems

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
				ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix ERC 11a: Wide dispersive indoor use of long-life articles and materials with low release **Sector of end use (SU):** SU 0: Other: SU03: Industrial uses: Uses of substances as such or in preparations at industrial sites SU 4: Manufacture of food products SU 5: Manufacture of textiles, leather, fur SU 6a: Manufacture of wood and wood products SU 6b: Manufacture of pulp, paper and paper products SU 7: Printing and reproduction of recorded media SU 12: Manufacture of plastics products, including compounding and conversion SU 14: Manufacture of basic metals, including alloys SU 15: Manufacture of fabricated metal products, except machinery and equipment **Subsequent service life relevant for that use?:** yes **Article category related to subsequent service life (AC):** AC 0: Other: Confidential, not included in the shared CSR
	2	Intermediate		**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 15: Use as laboratory reagent **Market sector by type of chemical product:** PC 0: Other: Confidential, not included in the shared CSR **Environmental release category (ERC):** ERC 1: Manufacture of substances ERC 2: Formulation of preparations ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates)

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
				ERC 6b: Industrial use of reactive processing aids ERC 6c: Industrial use of monomers for manufacture of thermoplastics ERC 6d: Industrial use of process regulators for polymerisation processes in production of resins, rubbers, polymers ERC 7: Industrial use of substances in closed systems ERC 8a: Wide dispersive indoor use of processing aids in open systems ERC 8b: Wide dispersive indoor use of reactive substances in open systems **Sector of end use (SU):** SU 9: Manufacture of fine chemicals SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement **Subsequent service life relevant for that use?:** no **Article category related to subsequent service life (AC):** AC 0: Other: Confidential, not included in the shared CSR
	3	Formulation and packaging		**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation PROC 15: Use as laboratory reagent **Market sector by type of chemical product:** PC 0: Other: Confidential, not included in the shared CSR

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
				Environmental release category (ERC): ERC 1: Manufacture of substances ERC 2: Formulation of preparations ERC 3: Formulation in materials ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates) ERC 8a: Wide dispersive indoor use of processing aids in open systems ERC 8b: Wide dispersive indoor use of reactive substances in open systems ERC 8d: Wide dispersive outdoor use of processing aids in open systems ERC 8f: Wide dispersive outdoor use resulting in inclusion into or onto a matrix **Sector of end use (SU):** SU 0: Other: SU03: Industrial uses: Uses of substances as such or in preparations at industrial sites SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) **Subsequent service life relevant for that use?:** no **Article category related to subsequent service life (AC):** AC 0: Other: Confidential, not included in the shared CSR
	4	Industrial end-use of products and articles		**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 7: Industrial spraying PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 10: Roller application or brushing PROC 11: Non industrial spraying PROC 13: Treatment of articles by dipping and pouring PROC 15: Use as laboratory reagent PROC 17: Lubrication at high energy conditions and in partly open process PROC 19: Hand-mixing with intimate contact and only PPE available.

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
				PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles **Market sector by type of chemical product:** PC 0: Other: Confidential, not included in the shared CSR **Environmental release category (ERC):** ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles ERC 5: Industrial use resulting in inclusion into or onto a matrix ERC 6b: Industrial use of reactive processing aids ERC 8a: Wide dispersive indoor use of processing aids in open systems ERC 8b: Wide dispersive indoor use of reactive substances in open systems ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix ERC 8d: Wide dispersive outdoor use of processing aids in open systems **Sector of end use (SU):** SU 0: Other: SU03 Industrial uses: Uses of substances as such or in preparations at industrial sites **Subsequent service life relevant for that use?:** no **Article category related to subsequent service life (AC):** AC 0: Other: Confidential, not included in the shared CSR

Table 5. Uses by professional workers

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
	5	Professional end-use of products and articles		**Process category (PROC):** PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 7: Industrial spraying

Confidential	IU number	Identified Use (IU) name	Substance supplied to that use	Use descriptors
				PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 10: Roller application or brushing PROC 11: Non industrial spraying PROC 13: Treatment of articles by dipping and pouring PROC 15: Use as laboratory reagent PROC 17: Lubrication at high energy conditions and in partly open process PROC 19: Hand-mixing with intimate contact and only PPE available. PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles **Market sector by type of chemical product:** PC 0: Other: Confidential, not included in the shared CSR **Environmental release category (ERC):** ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles ERC 5: Industrial use resulting in inclusion into or onto a matrix ERC 6b: Industrial use of reactive processing aids ERC 8a: Wide dispersive indoor use of processing aids in open systems ERC 8b: Wide dispersive indoor use of reactive substances in open systems ERC 8c: Wide dispersive indoor use resulting in inclusion into or onto a matrix ERC 8d: Wide dispersive outdoor use of processing aids in open systems **Sector of end use (SU):** **Subsequent service life relevant for that use?:** no **Article category related to subsequent service life (AC):**

Table 6. Uses by consumers

Confidential	IU number	Identified Use (IU) name	Use descriptors
	6	Consumer end-use of products and articles	**Chemical product category (PC):** PC 0: Other: Confidential, not included in the shared CSR **Environmental release category (ERC):** ERC 8a: Wide dispersive indoor use of processing aids in open systems ERC 8b: Wide dispersive indoor use of reactive substances in open systems **Subsequent service life relevant for that use?:** no **Article category related to subsequent service life (AC):** AC 0: Other: Confidential, not included in the shared CSR

Most common technical function of substance (what it does):

Confidential, not included in the shared CSR

Appendix 3 - Identity

1.1. Name and other identifiers of the substance

The substance **Syrups, hydrolyzed starch, hydrogenated** is a UVCB (origin: organic) having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details).

The following public name is used: Syrups, hydrolyzed starch, hydrogenated.

Table 1. Substance identity

CAS number:	68425-17-2
CAS name:	Syrups, hydrolyzed starch, hydrogenated
IUPAC name:	Syrups, hydrolyzed starch, hydrogenated
Description:	A complex combination obtained by the catalytic hydrogenation of hydrolyzed starch syrups. It consists primarily of Sorbitol, Maltitol, Maltotriitol and hydrogenated oligo and polysaccharides.
Molecular formula:	UVCB substance: not applicable
Molecular weight range:	>182 g/mol

Structural formula: not applicable

1.2. Composition of the substance

Name: Syrups, hydrolyzed starch, hydrogenated

Description: UVCB substance

Degree of purity: 100.0 % (w/w)

Table 2. Constituents

Constituent	Typical concentration	Concentration range	Remarks
D-glucitol EC no.: 200-061-5		0.0 — 80.0 % (w/w)	
4-O-a-D-glucopyranosyl-D-glucitol EC no.: 209-567-0		0.0 — 80.0 % (w/w)	
O-α-D-glucopyranosyl-(1→4)-O-α-D-glucopyranosyl-(1→4)-D-glucitol EC no.: 251-265-6		0.0 — 80.0 % (w/w)	
Syrups, hydrolyzed starch, hydrogenated, tetramers and higher oligomers		0.0 — 80.0 % (w/w)	
Water EC no.: 231-791-2		10.0 — 31.0 % (w/w)	

Appendix 4 - SIEF Agreement

SIEF and Joint Submission AGREEMENT

Syrups Hydrolysed Starch Hydrogenated

1. Definitions

(a) *Affiliate(s)* shall mean any legal or natural person, which directly or indirectly through one or more intermediaries owns, controls, is controlled by, or is under common control with, another legal person. For the purpose of this definition, a legal person shall be deemed to 'control' another legal person if it has the direct or indirect power to direct or cause the direction of the general management and policies of another legal person whether through the ownership of securities or capital stock, voting stock, by contract or otherwise. A legal person shall presumptively be deemed to control another legal person if it owns, directly or indirectly through one or more intermediaries and whether legally or beneficially fifty per cent (50%) or more of the outstanding voting securities or capital stock or other comparable equity or ownership interest of such legal person.. Only Affiliates subject to REACH registration of the Substance and that are members of the SIEF of the Substance and are named in this SIEF Agreement have the rights of Affiliates for purposes of this SIEF Agreement.

(b) *Joint Registration Group* shall mean the members of the SMJRRG Joint Registration Group (established by the *Joint Registration Group Agreement* of February 2010), of which Roquette Frères is a member.

(c) *Information* shall mean all studies, other scientific, statistical, or technical information or data, including but not limited to composition, characteristics, properties, processes and applications, and any other information in whatever form made available by a Party or generated by the Parties jointly, or licensed by or made available to the Joint Registration Group by third parties pursuant to or within the remit of this SIEF Agreement.

(d) *LoA* shall mean a letter of access to the Joint Registration Dossier granted by the Joint Registration Group to individual Parties as applicable to them and as attached as Annex 1 to this SIEF Agreement. The LoA entitles the Party (and its Affiliates) on a non-exclusive basis to refer to the information submitted to ECHA by the Lead Registrant for purposes of REACH registration, but it does not grant any additional rights except those specifically stated therein. In particular, it cannot be used, or transferred or relied upon, either for REACH or for any other purpose, by other legal entities, including affiliates of the Parties other than those named in the SIEF Agreement, unless those other legal entities would qualify for a free update of the original registration(s) pursuant to Article 5 (1) (c) of Commission Regulation (EC) No 340/2008.

(e) *Party* or *Parties* shall mean the parties to this SIEF Agreement who have *either* (i) signed this SIEF Agreement, and/or have paid for the LoA as laid down in 4. *or* (ii) following notification of this Agreement, have not communicated to the Lead Registrant their objection to become a member of the SIEF Agreement pursuant to 5.(k) and are not listed as 'inactivated' pre-registrants in REACH-IT.

(f) *REACH* shall mean Regulation (EC) No 1907/2006 and all subsequent Regulations, Decisions, and other measures adopted in connection thereto.

(g) *Joint Registration Dossier* shall cover the joint mandatory (Article 10 (a) (iv), (vi), (vii) and (ix) REACH) and joint voluntary (Article 10 (a) (v), and (b) REACH) parts of the REACH Registration Dossier for the Substance. The Joint Registration Dossier covers IUCLID core data for the data requirements for more than 1000 tonnes and the hazard assessment for the Chemical Safety Report, as well as guidance on safe use.

(h) *Substance* shall mean the substance listed in 2.(a) of this SIEF Agreement.

(i) All other terms used herein shall have the same meaning as under REACH.

2. Scope

(a) This SIEF Agreement covers the following substance, either by itself, as part of a multi-constituent substance, or as an intermediate:

Name (substance identification): Syrups, hydrolyzed starch, hydrogenated
EC number: not yet available
CAS No: 68425-17-2

Description: A complex combination obtained by the catalytic hydrogenation of hydrolyzed starch syrups. It consists primarily of Sorbitol, Maltitol, Maltotriitol and hydrogenated oligo and polysaccharides.

The Parties have agreed in previous communications on the identity and sameness of the Substance and are thus members of the same SIEF.

(b) This SIEF Agreement is applicable to all communications, actions and submissions made by the Parties individually or jointly within the scope of REACH in as far as these fall within the remit of SIEFs pursuant to Article 29 REACH.

(c) This SIEF Agreement is applicable to all members of the SIEF (including the members of the Joint Registration Group) of the Substance. Joint Registration Group members are represented for purposes of this SIEF Agreement by the Lead Registrant.

3. General Rules of Cooperation

(a) The Parties agree that Roquette Frères or its legal successor or another SIEF member assigned by it pursuant to 5. (f) below will act as the Lead Registrant for the Substance and will prepare, within the framework of the Joint Registration Group, the Joint Registration Dossier for REACH registration of the Substance as and in as far as required, and make requests pursuant to Article 10 (a) (xi) REACH as deemed necessary. Upon demand of ECHA, within the requested deadline and to the extent necessary, the Lead Registrant also agrees to complete the Joint Registration Dossier. Parties that are not members of the Joint

Registration Group will participate in the joint registration efforts via (g) below in conjunction with a LoA to be granted according to this SIEF Agreement.

(b) The Joint Registration Dossier will be prepared in time so that Parties can meet the November 30, 2010 registration deadline.

(c) In view of the tight work schedule, the Parties agree that the Lead Registrant will use its best efforts to develop the Joint Registration Dossier within the Joint Registration Group, and they acknowledge that the Lead Registrant has engaged reputable support to assist it in its efforts. The Parties will therefore not object or call into question the Joint Registration Dossier so prepared in as far as applicable to them, and the Parties hereby agree to the Joint Registration Dossier as developed by the Lead Registrant within the Joint Registration Group.

(d) The Lead Registrant undertakes in turn to regularly update the Parties in writing on the progress made on the Joint Registration Dossier as applicable to the Parties. The Lead Registrant may ask for cooperation and comments as it sees fit.

(e) The Lead Registrant shall pay the registration fee pursuant to Article 11 (4) REACH as invoiced by ECHA for the submission of the Joint Registration Dossier without undue delay.

(f) The Lead Registrant shall make the Joint Registration Dossier available for inspection by the Parties during business hours at the offices of McKenna Long & Aldridge LLP (2 Avenue de Tervueren, 1040 Brussels, Belgium) from September 15, 2010 to September 31, 2010. Any Party joining the SIEF after the inspection period is entitled to inspect the Joint Registration Dossier at the aforementioned premises after having taken an appointment.

(g) Provided the Party has fulfilled its payment obligations hereunder, the Lead Registrant shall inform the Party of the creation of a 'joint submission object' in REACH-IT and shall provide the valid security token number and the name of the joint submission. The Lead Registrant shall also inform the Parties of the submission of the Joint Registration Dossier to ECHA. The Lead Registrant shall further communicate the confirmation that the Joint Registration Dossier has been accepted as 'complete' and the registration number assigned pursuant to Article 20 (3) REACH.

4. Cost Sharing

(a) The price for the LoA is calculated by taking into account dossier preparation and management costs, data costs, advantage compensation, and handling fees, as well as any further expenses, *as follows*:

(i) *Total Joint Registration Dossier Preparation and Management Costs, excluding studies*

approximately € 180.000, to be shared equally.

(ii) *Data costs (studies)*

Exact figure not yet known. To be shared equally. Plus 15% administration cost for LoA applicants.

(b) Advantage Compensation

20% of (a) above.

(c) Handling fee

Fee for handling the LoA request and the joint submission, expected to be € 1000.

(d) Further expenses

Ongoing and future expenses to manage the Joint Registration Group during the registration and LoA issuing procedures, and additional unexpected costs that might arise through further requirements from the ECHA after registration should be added to the above figures.

(e) The Lead Registrant will calculate the price of the LoA by September 15, 2010 based on the number of Parties that confirmed their intention for 2010 registration by August 31, 2010 and will issue a proforma invoice or payment notice accordingly to be paid within 30 days of issuance by each Party; following payment, the joint submission tokens will be issued. A Party that does not pay a proforma invoice or payment notice within the 30 days of issuance shall at no time be entitled to participate in the joint submission and receive an LoA, or its LoA and permission to participate in the joint submission shall be considered as revoked.

(f) The final price will be calculated based on the amounts received on the proforma invoices and payment notices by November 30, 2010. Thereafter, final invoices will be issued. In case the amounts received from the proforma invoices and payment notices are not sufficient to cover the cost, tokens will only be issued after receipt of the amounts from the final invoices. The final price will be considered as a lump-sum fee for the future Parties to participate in joint submission or later registration. Should new studies have to be purchased or performed as deemed necessary by the Joint Registration Group or pursuant to ECHA's request, or technical responses to ECHA be necessary after registration, the Lead Registrant will issue instructions to issue additional invoices to be paid under the same terms if the cost cannot be covered by the fee paid by future Parties. No interest shall be applicable in either case on both sides. Due to the administrative burden upon the Joint Registration Group and the unlikelihood of new market entrants, no reimbursements shall be made. Should the number of registrants be significantly higher than the calculation, the additional fee originating from new Parties will be used to cover the running cost of the SIEF. The final settlement shall be handled by an independent auditor appointed by the Lead Registrant on June 1, 2022.

(g) The Lead Registrant will issue LoAs after receipt of a Party's payment and after the Party has had the option to inspect the Joint Registration Dossier as far as it is concerned by it pursuant to 3. (f).

(h) The Lead Registrant shall at all times account for the cost of the Joint Registration Dossier and shall keep records thereof for the duration of this SIEF Agreement. Any Party shall have the right to have the accounts audited at its own cost upon prior notice of at least five working days.

5. Miscellaneous Provisions

(a) *Assignment.* This SIEF Agreement is linked to the joint registration obligations of REACH and can therefore not be assigned or transferred by the Parties without prior approval of the

Lead Registrant unless the assignee is an Affiliate or successor in law subject to REACH registration of the Substance, or is an Only Representative or Third Party Representative replacing a previous Only Representative or Third Party Representative of the same principal and the assignment/transfer has been communicated to the Lead Registrant or its Trustee.

(b) *Communications.* All communications within the framework of this SIEF Agreement shall be done by electronic mail and shall be considered valid upon receipt of an automatic confirmation of receipt received by the sender. The Project Manager of the Joint Registration Group McKenna Long & Aldridge LLP acting on the behalf of the Joint Registration Group and the Lead Registrant shall install an email address or other electronic platform for communication within the SIEF. The parties agree to regularly and proactively communicate within this platform provided, and to answer any information and communication requests of the Lead Registrant within five working days at the latest unless the Lead Registrant expressly provides a longer response time. Unless other contact details are indicated below, the contact details available in REACH-IT shall be used at all times. The Parties shall at all times keep their REACH-IT contact details updated and functional. In case the REACH-IT contact details of a Party are not functional and no other valid and functional contact information has been provided below, the Lead Registrant shall be considered as released from any obligations under this SIEF Agreement.

(c) *Compliance.* The Parties shall at all times comply with the applicable laws, including EU competition law.

(d) *Confidentiality and Non-Use*. Each Party agrees to: (i) treat all Information as confidential and not disclose it to third parties, unless regulatory disclosure requirements are applicable; (ii) immediately advise the other Parties in writing of any disclosure or misuse by any Party or a third party of Information, as well as any request by competent authorities relating to disclosure of Information; (iii) disclose Information as required for legal and/or regulatory purposes including for purposes of REACH only in a form reflecting the minimum information required to be disclosed; (iv) use the Information only for purposes and as permitted hereunder; (v) not to analyze, test or reverse engineer or have analyzed, tested or reverse engineered any samples, formulas, combination of formulas or any technical or scientific methodology, chemistry or know-how provided by any of the Parties for their components, formulations or processes; (vi) not to file any patent, utility model or design application based upon Information or samples; *and* (vii) not to disclose Information to their employees, Affiliates, external experts and/or other consultants; unless the Party is an Only Representative or Third Party representative to the non-EU manufacturer or legal entity represented by the Third Party Representative, in which case it should only disclose Information on a strictly need-to-know basis to the extent permitted and absolutely necessary hereunder. Each Party shall have in place policies and procedures to ensure compliance herewith and shall ensure that the aforementioned entities and persons also have such policies and procedures in place.

The confidentiality and non-disclosure obligations above shall not apply to Information for which the receiving Party can reasonably demonstrate that such Information (i) was known to the receiving Party on a non-confidential basis prior to its disclosure pursuant to this SIEF Agreement; (ii) is publicly known at the time of disclosure or thereafter becomes publicly known without breach of the terms of this SIEF Agreement on the part of the receiving Party; (iii) becomes known to the receiving Party through disclosure by sources other than the disclosing Party, having a right to disclose such Information; (iv) was independently developed by the receiving Party without access to the disclosing Party's information, as

evidenced by documentary records; *or* (v) becomes subject to disclosure to governmental authorities with lawful authority to seek such Information.

Specific items of Information shall not fall within any exception merely because they are combined with more general Information falling within any exception. Likewise, any combination of specific items of Information shall not fall within any exception merely because the specific items fall within any exception, but only if the combination itself, and its principles of operation, fall within any exception.

The obligations on confidentiality and non-use shall remain in effect and shall survive the duration of this SIEF Agreement. In the event of non-compliance with the duties here above, Parties are entitled to exclude the breaching Party from any further cooperation hereunder by decision of an independent law firm appointed by the Lead Registrant upon recommendation of the Brussels Bar. The obligation to render compensation for damages in accordance with the applicable legal provisions shall remain unaffected.

(e) *Dispute resolution and applicable law.* Any dispute hereunder that cannot be settled amicably shall be resolved by arbitration with a single arbitrator to be appointed by the Brussels Bar. The arbitration rules of the International Court of Arbitration ("ICC") shall be applicable. The arbitration decision, including on the payment of the cost of arbitration, shall be binding on the Parties. The place of any hearing shall be Brussels and the language of the arbitration shall be English. Belgian law shall govern this SIEF Agreement. If at any time any provision of this SIEF Agreement is or becomes invalid or illegal in any respect, this shall have no effect on the validity of the remainder of this SIEF Agreement. The invalid provisions are to be replaced retroactively by provisions which come closest to achieving the objectives.

(f) *Duration and Termination.* This SIEF Agreement shall be in force until December 31, 2022, although its provisions under 5. (d), (e) and (h) shall survive its term indefinitely. Furthermore, the confidentiality obligations related to studies shall survive for 12 years after their first submission to ECHA, and all other confidentiality obligations shall survive until June 1, 2023.

The Lead Registrant has the right to terminate its functions as Lead Registrant provided another SIEF member has validly agreed to replace it within the SIEF, has agreed to the terms of this SIEF Agreement, and has taken up its functions accordingly. The other Parties must be informed about this replacement without undue delay.

Parties have the right to terminate this SIEF Agreement at the latest by June 30, 2010. The provisions under 5. (d), (e) and (h) shall survive termination as specified above.

(g) *Individual Responsibility.* Notwithstanding the cooperation within this SIEF Agreement, the Parties and their Affiliates remain individually responsible for compliance with REACH, in particular, but not limited to, their individual submission of information required under Article 11 (1) REACH

(h) *Liability.* The Lead Registrant shall only be liable to the other Parties in connection with the activities contemplated in this SIEF Agreement, including delays in the completion and submission of the Joint Registration Dossier, in case of gross negligence or wilful misconduct. He shall not be liable for consequential damage and lost profits. This limitation of liability does not apply in case of claims for death, personal injury or wilful misconduct. No warranty for acceptance of the Joint Registration Dossier or Information it contains, or

acceptance of a study by ECHA at dossier evaluation (according to Title VI REACH) is given.

(i) *Payments.* All payments due hereunder shall be net payments, *i.e.*, free of any bank or transfer charges or similar charges and without deduction of any taxes, levies or other dues payable. If payer is required to withhold any tax or to make any other deduction from any such payments, then the said payments shall be increased to the extent necessary to ensure that, after making of the required deduction or withholding, payee receives and retains (free from any liability in respect of any such deduction or withholding) a net sum equal to the sum which it would have received and so retained had no such deduction or withholding been made or required to be made (gross-up amount). If upon application of the beneficiary any withholding tax can be reduced, or refunded, or an exemption from withholding tax is granted, payer shall file on behalf of payee for such reduction, refund or exemption. Payee shall render any assistance to payer to obtain such withholding tax reduction, refund or exemption. Payer shall be entitled to any refund of withholding taxes. Indirect taxes, including but not limited to Value Added Tax ("VAT"), Goods and Service Tax ("GST"), service tax, business tax, as applicable pursuant to the relevant tax law, shall be borne by payer. However, payer is entitled to withhold any payment of indirect taxes unless payee has provided payer with a sufficient invoice for purposes of indirect taxation.

(j) *Rights.* This SIEF Agreement does not grant any ownership rights or change existing ownership rights to any of the Information provided under this SIEF Agreement to the Parties. Neither this SIEF Agreement nor any disclosure of Information shall vest any present or future rights in any patents, trade secrets, or property rights, and no license is granted. No legal entity or partnership for legal or tax purposes is created under this SIEF Agreement. The Parties are themselves responsible for any fiscal payments and declarations related to the working of this SIEF Agreement.

(k) *Validity / Entry into Effect.* This SIEF Agreement enters into effect between the Lead Registrant and the respective Party by (i) the Party filling in the required information below and returning a signed PDF copy of this SIEF Agreement, (ii) payment by the Party for the LoA, *or* (iii) the non-objection by the SIEF member to become a Party to this SIEF Agreement, *provided that* not more than half of the SIEF members have communicated their objection to this Agreement by June 15, 2010.

COMPANY:

_____

(Print company name and address)

(NON-EU/EEA) COMPANIES REPRESENTED :

_____

(In case the Party is an Only Representative ("OR"); indicate here the names of all the affiliated companies of one group represented by the OR to which this SIEF Agreement should be applicable; In case the OR has pre-registered for several groups of companies, he must sign separate SIEF Agreements for each of the groups; Likewise, if a Third Party Representative ("TPR")[1] represents several independent companies for the Substance, he must sign separate SIEF agreements for each of the independent companies represented)

AUTHORIZED REPRESENTATIVE:

_____

(Print name of Representative authorized to sign this SIEF Agreement)

SIGNATURE:

_____

(Signature of Authorized Representative)

CONTACT INFORMATION:

_____

(Print contact details for person responsible for SIEF communication)

[1] For information on submission of company identity information by TPRs, documentation is available on http://cefic.org/templates/shwPublications.asp?HID=750&T=812 under "Joint submission process in REACH-IT".

Annex 1

MODEL LETTER OF ACCESS

[address of regulatory authority]

Letter of Access for the registration of the substance Syrups Hydrolysed starch Hydrogenated under *REACH*

Dear Sirs,

The Joint Registration Group for the registration of the substance SMJRRG under *REACH* (here thereafter referred to as "the Joint Registration Group") agrees that the data, studies, summaries, waiving argumentations, reasoning of testing proposals and/or assessments owned or subject to a use right by the members of the Joint Registration Group and submitted by the Joint Registration Group in support of the registration under *REACH* of the following Substance

Name (substance identification): Syrups, hydrolyzed starch, hydrogenated
EC number: [not yet available]
CAS No: 68425-17-2
Description: A complex combination obtained by the catalytic hydrogenation of hydrolyzed starch syrups. It consists primarily of Sorbitol, Maltitol, Maltotriitol and hydrogenated oligo and polysaccharides.

(hereinafter collectively referred to as the "Joint Registration Dossier"), may be referred to

[Company XYZ / List of Affiliates] (hereafter the "Applicant")

in order to support the Applicant's registration of the above-mentioned substance under REACH.

In his registration, the Applicant acts: *(please tick appropriate box)*

☐ for himself

☐ as an Only Representative pursuant to Article 8 REACH for the following non-EU manufacturer: ____

☐ as a Third Party Representative[2] pursuant to Article 4 REACH.

In the Joint Registration Dossier, the Applicant would like to be covered concerning the following parts/documents: *(please tick appropriate box(es))*

[2] *See* CEFIC April 2009 Paper on Joint Submission Process in REACH-IT p. 8. If a SIEF member is hidden behind a TPR, the TPR will receive the token and the Joint Submission name from the Lead Registrant. The TPR will bring this information back to his customer. The SIEF member himself must confirm his membership to the Joint Submission and his identity will be disclosed to the Lead Registrant only. The SIEF member must submit the substance dossier himself.

☐ Mandatory joint parts of the Joint Registration Dossier (Article 10 (a) (iv), (vi), (vii) and (ix) REACH)

☐ 'Opt-out' pursuant to Article 11 (3) for the following mandatory joint parts:

Article 10 (a)

☐ (iv)

☐ (vi)

☐ (vii)

☐ (ix)

On request, the Applicant may receive a summary of the *Information* submitted by the Joint Registration Group in support of the registration under *REACH.*

The right to refer to the Joint Registration Dossier is subject to the following restrictions:

1. The right of referral only gives access to the Joint Registration Dossier of the substance for the registration as specified above.

2. The right of referral is solely granted in favor of the Applicant and the Affiliates listed herein and is not transferable to any other entity or person.

3. Unless otherwise specified below, the Applicant is not authorized to receive any copies of the Joint Registration Dossier nor is the Applicant authorized to inspect or view the Joint Registration Dossier at ECHA or any related specific document in whole or in part, outside the general inspection period granted by the Joint Registration Group.

4. This Letter of Access shall in no event be construed as granting the Applicant any property rights whatsoever in the Joint Registration Dossier.

5. Nothing in this letter shall require *the Joint Registration Group members* to file any additional data.

In any event and regardless of the rights and restrictions set forth above, the Applicant shall always receive the proposed classification and labeling as well as the PNECs and DNELs.

This Letter of Access does not create any rights for third parties or any liability towards third parties in relation to the data for which access is granted.

Signature: Authorized Representative of the Joint Registration Group.

The Applicant hereby declares that he is aware of, agrees and complies with the provisions of the SIEF Agreement issued by the Lead Registrant Roquette Frères, which shall apply in its entirety in addition to the provisions set out hereunder.

Appendix 5 - LoA price calculation (incl. budgets and study valuation)

SMJRRG : LOA calculation (4 SIEF Members)

	TOTAL	Above 1000 tons	100-1000 tons	10-100 tons	Intermediate
2010 Budget excluding study costs	€ 173,505	€ 43,376	€ 43,376	€ 43,376	€ 43,376
2011 Budget	€ 23,500	€ 5,875	€ 5,875	€ 5,875	€ 5,875
Study Costs - WGS	€ 8,539	€ 2,135	€ 2,135	€ 2,135	€ 2,135
Study Costs - Towa/Mitsubishi *	€ 19,205	€ 4,801	€ 4,801	€ 4,801	€ 4,801
Study Costs - Internal	€ 296,147	€ 74,037	€ 25,974	€ 9,320	€ 731
Expenses MLA	€ 650	€ 163	€ 163	€ 163	€ 163
Expenses Intertek	€ 612	€ 153	€ 153	€ 153	€ 153
TOTAL	**€ 522,158**	**€ 130,540**	**€ 82,324**	**€ 65,670**	**€ 57,080**
Admin cost 20% on everything except Study Costs		€ 9,913	€ 9,913	€ 9,913	€ 9,913
Admin cost 15% on Study Costs		€ 12,146	€ 4,937	€ 2,438	€ 1,150
TOTAL WITH ADMIN COST		**€ 152,599**	**€ 92,237**	**€ 75,583**	**€ 66,994**
Handling Fee		€ 1,000	€ 1,000	€ 1,000	€ 1,000
TOTAL LOA PRICE		**€ 153,599**	**€ 93,237**	**€ 76,583**	**€ 67,994**

Notes

* The Towa/Mitsubishi licence fee is marked up to take 4 SIEF members into account because reduction on price for co-owner/license had been granted to one SMJRRG member.

APPENDIX 5

SMJRRG Budget

SMJRRG Management for non crystallizing sorbitol and maltitol		2010	2011
Drafting of SMJRRG Agreement based on MLA model (compatible with VCI and CEFIC model). Negotiating and follow-up work to finalize Agreement (estimate of three days for changes to agreement and negotiation). In case group needs less, fees will be reduced	MLA	€ 10,000	€ -
Steering Committee - organization, preparation of agenda, attendance, drafting of minutes	MLA	€ 31,680	€ -
Administration of ad-hoc TC working groups (review of minutes)	MLA	€ 2,000	€ -
Accounting	MLA	€ 4,000	€ 4,250
General Management of the Consortium	MLA	€ 4,000	€ 4,250
SIEF communication - estimate	MLA	€ 15,000	€ 5,000
MLA LOA on-line tool	MLA	€ 1,500	€ -
Legal advice (negotiation of license agts, drafting of SIEF agts, etc.) - estimate	MLA	€ 15,000	€ 5,000
Total Legal and Accounting support Estimate		**€ 83,180**	**€ 18,500**
Dossier Preparation		**2010**	**2011**
Data collection and read-across	Intertek	€ 12,000	€ -
Robust study summaries in IUCLID 5 (including toxicokinetics assessment)	Intertek	€ 16,000	€ -
Endpoint summary records in IUCLID 5/hazard assessment/baseline CSR	Intertek	€ 9,000	€ -
Coordination & Communication to members, ad-hoc technical working groups & mtgs	Intertek	€ 43,000	€ -
Literature search	Intertek	€ 4,200	€ -
Additonal budget	Intertek	€ 6,125	€ -
Budget reserve after submission	Intertek	€ -	€ 5,000
Licensing of sudies	WGS	€ 8,539	€ -
Licensing of studies (to be divided between Cargill, Syral and DHW)	Towa / Mitsubishi	€ 14,404	€ -
Total Dossier Preparation Costs		**€ 113,268**	**€ 5,000**
GRAND TOTAL		**€ 196,448**	**€ 23,500**

APPENDIX 5

SMJRRG - Data Used in Registration Dossier (excl. WGS and Towa)

REACH endpoint	Annex	IUCLID endpoint	Endpoint	Owner	Year	Title	Klimisch Rating	Study status	Endpoint type	Fleischer et al. Average price large labs [€]	current value of study	Reduction Factor	Value all LoA (€)	Value of Robust study summary	Value of the endpoint for LoA
7.1	VII	4.01	State of the Substance	Roquette Freres	2010	Safety Data Sheet	2	weight of evidence	Robust Study Summary		0 €	50%	0 €	0 €	0 €
7.1	VII	4.01	State of the Substance	Roquette Freres	2010	Safety Data Sheet	2	weight of evidence	Robust Study Summary		0 €	50%	0 €	0 €	0 €
7.2.	VII	4.02	Melting/freezing point	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
7.3	VII	4.03	Boiling Point	Public	1989	The Merck Index: An Encyclopedia of Chemicals. Drugs. and Biologicals (11th Edition)	2	weight of evidence	Robust Study Summary		0 €	50%	0 €	0 €	0 €
7.3	VII	4.03	Boiling Point	Public	2000	CRC Handbook of Chemistry and Physics (81st Edition)	2	weight of evidence	Robust Study Summary		0 €	50%	0 €	0 €	0 €
7.3	VII	4.03	Boiling Point	Roquette Freres	2010	Safety Data Sheet	4	weight of evidence	Robust Study Summary		0 €	50%	0 €	0 €	0 €
7.3	VII	4.03	Boiling Point	Roquette Freres	2010	Safety Data Sheet	4	weight of evidence	Robust Study Summary		0 €	50%	0 €	0 €	0 €
7.4.	VII	4.04	Relative density	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
7.14.	VII	4.05	Granulometry	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
7.5	VII	4.06	Vapour Pressure	Sorbitol and Maltitol Joint REACH Registration Group	2010	Alternative Methodology for Determination of Vapour Pressure	2	key study	Robust Study Summary	3,211 €	3,211 €	50%	0 €	0 €	0 €
7.8.	VII	4.07	Partition coefficient n-octanol/water	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
7.7	VII	4.08	Water Solubility	Public	2006	The Merck Index: An Encyclopedia of Chemicals. Drugs. and Biologicals (14th Edition)	2	weight of evidence	Robust Study Summary		0 €	50%	0 €	0 €	0 €
7.7	VII	4.08	Water Solubility	Public	2008	CRC Handbook of Chemistry and Physics (89th Ed)	2	weight of evidence	Robust Study Summary		0 €	50%	0 €	0 €	0 €
7.7	VII	4.08	Water Solubility	Roquette Freres	2010	Safety Data Sheet	4	weight of evidence	Robust Study Summary		0 €	50%	0 €	0 €	0 €
7.7	VII	4.08	Water Solubility	Roquette Freres	2010	Safety Data Sheet	4	weight of evidence	Robust Study Summary		0 €	50%	0 €	0 €	0 €
7.6.	VII	4.10	Surface tension	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
7.9.	VII	4.11	Flash-point	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €

7.12.	VII	4.12	Self-ignition temperature	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
7.10.	VII	4.13	Flammability	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
7.11.	VII	4.14	Explosive properties	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
7.13.	VII	4.15	Oxidising properties	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
7.15.	IX	4.17	Stability in organic solvents and identity of relevant degradation products	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
7.16.	IX	4.21	Dissociation constant	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
7.17	IX	4.22	Viscosity	Public	1989	The Merck Index: An Encyclopedia of Chemicals. Drugs. and Biologicals (11th Edition)	2	weight of evidence	Robust Study Summary		0 €	50%	0 €	0 €	0 €
7.17	IX	4.22	Viscosity	Roquette Freres	2010	Safety Data Sheet	4	weight of evidence	Robust Study Summary		0 €	50%	0 €	0 €	0 €
7.17	IX	4.22	Viscosity	Roquette Freres	2010	Safety Data Sheet	4	weight of evidence	Robust Study Summary		0 €	50%	0 €	0 €	0 €
9.2.2.1	VIII	5.1.2	Hydrolysis	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
9.2.1	X	5.2.2	Degradation: biotic: further tests	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
9.3.4	X	5.3.1	Environmental fate and behavior: further tests	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
9.3.1.	VIII	5.4.1	Adsorption/desorption screening	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
9.1.6.2	IX	6.1.2	Fish short term toxicity test on embryo and sac-fry	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
9.1.6.3	IX	6.1.2	Fish juvenile growth test	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
9.4.1	IX	6.1.3	Short term toxicity to invertebrates (terrestrial)	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
9.4.4	X	6.1.3	Long term toxicity testing on invertebrates (terrestrial)	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €

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9.1.5	IX	6.1.4	Long term study on invertebrates (daphnia)	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
9.4.2	IX	6.1.4	Effects on soil microorganisms	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
9.1.4.	VIII	6.1.7	Activated sludge respiration inhibition	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
9.5.1	X	6.2	Long term toxicity to sediment organisms	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
9.4.3	IX	6.3.3	Short term toxicity to plants	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
9.4.6	X	6.3.3	Long term toxicity testing on plants	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
9.6.1	X	6.3.5	Long term or reproductive toxicity on birds	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
8.8.1	VIII	7.1	Basic Toxicokinetics	Roquette Freres	1972	Not applicable, see reference list of studies used for Toxicokinetics assessment	not determined	supporting study	Reference to studies owned by Roquette	49,161 €	24,581 €	50%	12,290 €	0 €	12,290 €
8.8.1	VIII	7.1	Basic Toxicokinetics	Sorbitol and Maltitol Joint REACH Registration Group	2010	Toxicokinetics (assessment)	not determined	Assessment	Assessment	49,161 €	4,638 €	100%	4,638 €	0 €	4,638 €
8.8.1	VIII	7.01	Basic Toxicokinetics	Roquette Freres	1982	Study of the in vivo digestion of Lycasin(R) 80/55 in the rat.	not determined	weight of evidence	Reference to study		0 €	50%	0 €	0 €	0 €
8.8.1	VIII	7.01	Basic Toxicokinetics	Public	1982	The metabolism of maltitol in the rat	2	weight of evidence	Reference to study		0 €	50%	0 €	0 €	0 €
8.8.1	VIII	7.01	Basic Toxicokinetics	Roquette Freres	1982	Study of the in vivo digestion of Lycasin(R) 80/55 in the rat.	not determined	weight of evidence	Reference to study		0 €	50%	0 €	0 €	0 €
8.8.1	VIII	7.01	Basic Toxicokinetics	Roquette Freres	1984	Study of the in vivo digestion of Lycasin(R) 80/55 in the rat. Volume III. A comparative study on fed and fasting rats	not determined	weight of evidence	Reference to study		0 €	50%	0 €	0 €	0 €
8.8.1	VIII	7.01	Basic Toxicokinetics	Roquette Freres	1982	Digestion in vitro by enzymes of the intestinal mucosa of rat and man of Lycasin(R) 80/55 and of its main fractions with a comparison with several di- and polysaccharides.	not determined	weight of evidence	Reference to study		0 €	50%	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	Public	1976	Metabolism and caloric utilization of orally administered maltitol-14C in rat, dog, and man	2	weight of evidence	Reference to study		0 €	50%	0 €	0 €	0 €

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8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	Public	1983	Digestion of Maltitol in Man, Rat, and Rabbit	2	weight of evidence	Reference to study		0 €	50%	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	Public	1982	The metabolic fate of hydrogenated glucose syrups	2	weight of evidence	Reference to study		0 €	50%	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	Public	1982	The metabolism of maltitol in the rat	2	weight of evidence	Reference to study		0 €	50%	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	Roquette Freres	1982	A study of the urinary excretion and risks of accumulation of maltitol in certain organs of rats fed with Lycasin	not determined	weight of evidence	Reference to study		0 €	50%	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	Public	1991	Metabolic fate of ingested [14C]-maltitol in man	not determined	weight of evidence	Reference to study		0 €	50%	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	Public	1990	Digestion and absorption in the human intestine of three sugar alcohols. Gastroenterology	not determined	weight of evidence	Reference to study		0 €	50%	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	Roquette Freres	1972	Acute toxicological test of sorbitol	not determined	weight of evidence	Reference to study		0 €	50%	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	Roquette Freres	1972	A study of toxicity using sorbitol	not determined	weight of evidence	Reference to study		0 €	50%	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	Roquette Freres	1982	6-Month Oral Toxicity in the Beagle. Sorbitol 6-Month Toxicity Study in the Beagle Dog Complementary Biochemical Examinations	not determined	weight of evidence	Reference to study		0 €	50%	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	Roquette Freres	1982	A 13 week toxicity study of per os administered product in dogs.	not determined	weight of evidence	Reference to study		0 €	50%	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	Public	1972	Teratologic Evaluation of FDA 71-31 (Sorbitol)	not determined	weight of evidence	Reference to study		0 €	50%	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	Roquette Freres	1983	Three Generation Reproduction Toxicity Studies	not determined	weight of evidence	Reference to study		0 €	50%	0 €	0 €	0 €
8.5.2.	VIII	7.2.2	Acute toxicity: inhalation	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
8.5.3.	VIII	7.2.3	Acute toxicity: dermal	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
8.1.1	VIII	7.3.1	In-vivo skin corrosion/irritation	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
8.6.2	IX	7.5.1	Sub-chronic toxicity study	Roquette Freres	1982	A 13 week toxicity study of per os administered product in dogs.	2	key study	Robust Study Summary	119,450 €	119,450 €	50%	59,725 €	0 €	59,725 €

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8.4	IX	7.6.1	Mutagenicity: in vivo (somatic cell genotoxicity)	Roquette Freres	1981	Research of the possible mutagenic activity of Lycasin(R) by the micronucleus test on mouse.	2	key study	Robust Study Summary	11,785 €	11,785 €	50%	5,893 €	0 €	5,893 €
8.4.1	VII	7.6.1	Mutagenicity: In-vitro gene mutation in bacteria (AMES)	Roquette Freres	1978	Report of experiments on the mutagen potential of Lycasin(R) 80/55 Ref. 62157 (Ames test).	2	key study	Robust Study Summary	3,204 €	3,204 €	50%	1,602 €	0 €	1,602 €
8.4.2	VIII	7.6.1	Mutagenicity: in vitro cytogenicity study in mammalian cells	Roquette Freres	1982	In vitro chromosome aberrations in Chinese hamster ovary cells with Lycasin(R).	2	key study	Robust Study Summary	19,217 €	19,217 €	50%	9,609 €	0 €	9,609 €
8.4.3	VIII	7.6.1	Mutagenicity: in vitro gene mutation study in mammalian cells (mouse lymphoma)	Roquette Freres	1982	Mouse Lymphoma Forward Mutation Assay. Lycasin. Final Report.	2	key study	Robust Study Summary	15,644 €	15,644 €	50%	7,822 €	0 €	7,822 €
8.7.1.	VIII	7.8.1	Screening for reproductive/developmental toxicity	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
8.7.3	IX	7.8.1	Toxicity to reproduction	Roquette Freres	1983	Lycasin® 80/55 Three Generation Reproduction Toxicity Studies	2	supporting study	Robust Study Summary	313,967 €	0 €	50%	0 €	1,000 €	1,000 €
9.1.6.1	IX	6.1.2	Fish early life stage toxicity test	Sorbitol and Maltitol Joint REACH Registration Group				data waiving	statement		0 €	50%	0 €	0 €	0 €
8.8.1 / 8.6.3 / 8.7.3 / 8.7.2	VIII	7.1 / 7.5.1 / 7.8.1 / 7.8.2	Toxicokinetics, metabolism and distribution / Long term repeated dose toxicity (>=12 months): oral / Toxicity to reproduction / Developmental Toxicity / Teratogenicity	Public	1993	Safety Assessment of Hydrogenated Starch Hydrolysates	not determined (7.1) / 2 (7.5.1, 7.8.1) / 1 (7.8.2)	key study (7.8.1, 7.8.2) / supporting study (7.5.1) / weight of evidence (7.1)	Reference to study		0 €	50%	0 €	0 €	0 €
8.5.1 / n.a.	VII	7.2.1 / 7.2.4	Acute toxicity: oral / Acute toxicity: other rutes	Roquette Freres	1982	ACUTE TOXICITY OF LYCASIN ® 80/55 DETERMINATION OF THE LD 50 IN THE RAT	2	key study	Robust Study Summary	1,639 €	1,639 €	50%	820 €	0 €	820 €
8.5.1 / n.a.	VII	7.2.1 / 7.2.4	Acute toxicity: oral / Acute toxicity: other rutes	Roquette Freres	1982	ACUTE TOXICITY OF LYCASIN® 80/55 DETERMINATION OF THE LD 50 IN MICE	2	supporting study	Robust Study Summary	1,639 €	0 €	50%	0 €	500 €	500 €
8.6.3 / 8.9.1	X	7.5.1 / 7.7	Long term repeated dose toxicity (>=12 months):oral / Carcinogenicity	Cargill Incorporated	1992	Combined Chronic Toxicity/Carcinogenicity Study in Rats - Carcinogenicity Study	1	key study	Robust Study Summary	382,500 €	382,500 €	50%	191,250 €	0 €	191,250 €
8.6.3 / 8.9.1	X	7.5.1 / 7.7	Long term repeated dose toxicity (>=12 months):oral / Carcinogenicity	Roquette Freres	1984	24 MONTHS SAFETY STUDY OF LYCASIN® 80/55 ON RAT	1	supporting study	Robust Study Summary	382,500 €	0 €	50%	0 €	1,000 €	1,000 €
															296,147 €

APPENDIX 5

SMJRRG - Data Cost Calculation per Tonnage Band (excl. WGS and Towa)

REACH endpoint	Annex	IUCLID endpoint	Endpoint	Above 1000 tonnes Annex VII-X	100 - 1000 tonnes Annex VII-IX	10 - 100 tonnes Annex VII-VII	1 ton or transport. Interm. >1000 Annex VII
7.1	VII	4.01	State of the Substance	0 €	0 €	0 €	0 €
7.1	VII	4.01	State of the Substance	0 €	0 €	0 €	0 €
7.2.	VII	4.02	Melting/freezing point	0 €	0 €	0 €	0 €
7.3	VII	4.03	Boiling Point	0 €	0 €	0 €	0 €
7.3	VII	4.03	Boiling Point	0 €	0 €	0 €	0 €
7.3	VII	4.03	Boiling Point	0 €	0 €	0 €	0 €
7.3	VII	4.03	Boiling Point	0 €	0 €	0 €	0 €
7.4.	VII	4.04	Relative density	0 €	0 €	0 €	0 €
7.14.	VII	4.05	Granulometry	0 €	0 €	0 €	0 €
7.5	VII	4.06	Vapour Pressure	0 €	0 €	0 €	0 €
7.8.	VII	4.07	Partition coefficient n-octanol/water	0 €	0 €	0 €	0 €
7.7	VII	4.08	Water Solubility	0 €	0 €	0 €	0 €
7.7	VII	4.08	Water Solubility	0 €	0 €	0 €	0 €
7.7	VII	4.08	Water Solubility	0 €	0 €	0 €	0 €
7.7	VII	4.08	Water Solubility	0 €	0 €	0 €	0 €
7.6.	VII	4.10	Surface tension	0 €	0 €	0 €	0 €
7.9.	VII	4.11	Flash-point	0 €	0 €	0 €	0 €
7.12.	VII	4.12	Self-ignition temperature	0 €	0 €	0 €	0 €
7.10.	VII	4.13	Flammability	0 €	0 €	0 €	0 €
7.11.	VII	4.14	Explosive properties	0 €	0 €	0 €	0 €
7.13.	VII	4.15	Oxidising properties	0 €	0 €	0 €	0 €
7.15.	IX	4.17	Stability in organic solvents and identity of relevant degradation products	0 €	0 €	0 €	0 €
7.16.	IX	4.21	Dissociation constant	0 €	0 €	0 €	0 €
7.17	IX	4.22	Viscosity	0 €	0 €	0 €	0 €
7.17	IX	4.22	Viscosity	0 €	0 €	0 €	0 €
7.17	IX	4.22	Viscosity	0 €	0 €	0 €	0 €
9.2.2.1	VIII	5.1.2	Hydrolysis	0 €	0 €	0 €	0 €
9.2.1	X	5.2.2	Degradation: biotic: further tests	0 €	0 €	0 €	0 €
9.3.4	X	5.3.1	Environmental fate and behavior: further tests	0 €	0 €	0 €	0 €
9.3.1.	VIII	5.4.1	Adsorption/desorption screening	0 €	0 €	0 €	0 €
9.1.6.2	IX	6.1.2	Fish short term toxicity test on embryo and sac-fry	0 €	0 €	0 €	0 €
9.1.6.3	IX	6.1.2	Fish juvenile growth test	0 €	0 €	0 €	0 €
9.4.1	IX	6.1.3	Short term toxicity to invertebrates (terrestrial)	0 €	0 €	0 €	0 €

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9.4.4	X	6.1.3	Long term toxicity testing on invertebrates (terrestrial)	0 €	0 €	0 €	0 €
9.1.5	IX	6.1.4	Long term study on invertebrates (daphnia)	0 €	0 €	0 €	0 €
9.4.2	IX	6.1.4	Effects on soil microorganisms	0 €	0 €	0 €	0 €
9.1.4.	VIII	6.1.7	Activated sludge respiration inhibition	0 €	0 €	0 €	0 €
9.5.1	X	6.2	Long term toxicity to sediment organisms	0 €	0 €	0 €	0 €
9.4.3	IX	6.3.3	Short term toxicity to plants	0 €	0 €	0 €	0 €
9.4.6	X	6.3.3	Long term toxicity testing on plants	0 €	0 €	0 €	0 €
9.6.1	X	6.3.5	Long term or reproductive toxicity on birds	0 €	0 €	0 €	0 €
8.8.1	VIII	7.1	Basic Toxicokinetics	12,290 €	12,290 €	12,290 €	0 €
8.8.1	VIII	7.1	Basic Toxicokinetics	4,638 €	4,638 €	4,638 €	0 €
8.8.1	VIII	7.01	Basic Toxicokinetics	0 €	0 €	0 €	0 €
8.8.1	VIII	7.01	Basic Toxicokinetics	0 €	0 €	0 €	0 €
8.8.1	VIII	7.01	Basic Toxicokinetics	0 €	0 €	0 €	0 €
8.8.1	VIII	7.01	Basic Toxicokinetics	0 €	0 €	0 €	0 €
8.8.1	VIII	7.01	Basic Toxicokinetics	0 €	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	0 €	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	0 €	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	0 €	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	0 €	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	0 €	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	0 €	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	0 €	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	0 €	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	0 €	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	0 €	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	0 €	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	0 €	0 €	0 €	0 €
8.8.1	VIII	7.1	Toxicokinetics, metabolism and distribution	0 €	0 €	0 €	0 €
8.5.2.	VIII	7.2.2	Acute toxicity: inhalation	0 €	0 €	0 €	0 €
8.5.3.	VIII	7.2.3	Acute toxicity: dermal	0 €	0 €	0 €	0 €
8.1.1	VIII	7.3.1	In-vivo skin corrosion/irritation	0 €	0 €	0 €	0 €
8.6.2	IX	7.5.1	Sub-chronic toxicity study	59,725 €	59,725 €	0 €	0 €
8.4	IX	7.6.1	Mutagenicity: in vivo (somatic cell genotoxicity)	5,893 €	5,893 €	0 €	0 €
8.4.1	VII	7.6.1	Mutagenicity: In-vitro gene mutation in bacteria (AMES)	1,602 €	1,602 €	1,602 €	1,602 €
8.4.2	VIII	7.6.1	Mutagenicity: in vitro cytogenicity study in mammalian cells	9,609 €	9,609 €	9,609 €	0 €
8.4.3	VIII	7.6.1	Mutagenicity: in vitro gene mutation study in mammalian cells (mouse lymphoma)	7,822 €	7,822 €	7,822 €	0 €

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8.7.1.	VIII	7.8.1	Screening for reproductive/developmental toxicity	0 €	0 €	0 €	0 €
8.7.3	IX	7.8.1	Toxicity to reproduction	1,000 €	1,000 €	0 €	0 €
9.1.6.1	IX	6.1.2	Fish early life stage toxicity test	0 €	0 €	0 €	0 €
8.8.1 / 8.6.3 / 8.7.3 / 8.7.2	VIII	7.1 / 7.5.1 / 7.8.1 / 7.8.2	Toxicokinetics, metabolism and distribution / Long term repeated dose toxicity (>=12 months): oral / Toxicity to reproduction / Developmental Toxicity / Teratogenicity	0 €	0 €	0 €	0 €
8.5.1 / n.a.	VII	7.2.1 / 7.2.4	Acute toxicity: oral / Acute toxicity: other rutes	820 €	820 €	820 €	820 €
8.5.1 / n.a.	VII	7.2.1 / 7.2.4	Acute toxicity: oral / Acute toxicity: other rutes	500 €	500 €	500 €	500 €
8.6.3 / 8.9.1	X	7.5.1 / 7.7	Long term repeated dose toxicity (>=12 months):oral / Carcinogenicity	191,250 €	0 €	0 €	0 €
8.6.3 / 8.9.1	X	7.5.1 / 7.7	Long term repeated dose toxicity (>=12 months):oral / Carcinogenicity	1,000 €	0 €	0 €	0 €
				296,147 €	**103,897 €**	**37,280 €**	**2,922 €**