

23-04-2018

EJ. AH: 8/2018/5
Přílohy:

Agreement on rights to use individual studies for registration under REACH

between

Berufsgenossenschaft Rohstoffe und chemische Industrie
Kurfürsten-Anlage 62
69115 Heidelberg
Germany
(hereinafter "BG RCI")

and

the BG RCI Member Company as an individual legal entity (please insert the following details)

Name of company:	Axxence Slovakia s.r.o.
BG RCI Member Company's registration number:	VAT: SK2020360034
Contact person:	Ing. Lubomíra Rapošova
Complete address:	Mickiewiczova 9, 811 07 Bratislava, Slovakia
E-mail address:	lubka.raposova@axxence.sk
Phone number:	+421903 911 941
(hereinafter "COMPANY")	

Whereas:

COMPANY is manufacturer/importer/only representative and under an obligation to register the substance 3-methylbutan-1-ol (add name of substance) (CAS No.: 123-51-3 or BG No.: 95) (hereinafter "Substance") according to "Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)" (hereinafter "REACH").

BG RCI owns the study/studies listed in Annex 1 necessary for the registration under REACH of the Substance. COMPANY is interested in acquiring rights to use this study/these studies for REACH registration purposes for itself.

Therefore, BG RCI and COMPANY agree as follows:

1 Provision of study/studies listed in Annex 1 and/or Right of Use

- 1.1 BG RCI provides COMPANY with a Letter of Access with permission to refer to study/studies listed in Annex 1 for the Substance.
- 1.2 Provided that COMPANY is a BG RCI Member Company as shown by the valid BG RCI Member Company's registration number, BG RCI grants COMPANY for an indefinite period of time the non-transferable and non-terminable right to use the full study report of the study/studies listed in Annex 1 provided by BG RCI, (which includes the right to generate a robust study summary as well as the permission to refer to the full study reports), solely for the purpose of registration of the Substance according to REACH as well as to fulfil other requirements under REACH.

- 1.3 BG RCI issues the Letter of Access in Annex 2 for the right of use. COMPANY is entitled to present this Letter of Access to the European Chemicals Agency (ECHA) upon registration of the substance as well as to other authorities (if required).
- 1.4 This Agreement shall under no circumstances be construed as granting the COMPANY any property rights other than those specified in Subsection 1.3 hereof in the study/studies listed in Annex 1 and shall not affect the right of BG RCI to grant any third party any right to use the study/studies listed in Annex 1 for REACH or other purposes.

2 Consideration

For the rights according to Article 1 of this Agreement, COMPANY will pay no money to BG RCI because COMPANY is a BG RCI Member Company.

3 Confidentiality

3.1 COMPANY agrees:

3.1.1 To treat all information contained in the study documents provided hereunder or otherwise disclosed by BG RCI in relation to the study/studies listed in Annex 1 (collectively "Information") as confidential and to use the Information only for the purpose specified in, and according to the terms of, this Agreement. COMPANY undertakes to advise BG RCI immediately in writing of any disclosure or misuse by a third party of Information as well as of any request by competent authorities relating to the disclosure of that Information insofar and as soon as COMPANY obtains knowledge thereof.

3.1.2 To make all reasonable efforts to ensure that disclosure of such Information as required for REACH regulatory purposes, shall only take place in a form (for example short summaries where possible) reflecting the minimum information required to be disclosed.

3.1.3 To make it available only to those employees or COMPANY'S external consultants (including their employees) who need to have access to such information for the purpose specified in Article 1.2 of this Agreement and who are contractually or otherwise obligated to keep it confidential. COMPANY shall be responsible and accountable for the compliance of their external consultants (including their employees) with the obligations of this Article 3.

3.2 Notwithstanding Article 3.1, in the event COMPANY as recipient of Information, makes a reasonable determination that it is required to disclose such Information pursuant to a governmental and/or judicial obligation or order other than according to the requirements under REACH, COMPANY will inform BG RCI in writing in due time of the disclosure and ask the recipient to maintain confidentiality.

3.3 The obligations specified in Articles 3.1 and 3.2 above shall not apply to information for which COMPANY can reasonably demonstrate that such Information:

3.3.1 was known to COMPANY on a non-confidential basis prior to its disclosure pursuant to this Agreement;

3.3.2 is publicly known at the time of disclosure or becomes publicly known thereafter without breach of the terms of this Agreement on the part of COMPANY;

3.3.3 becomes known to COMPANY (without any restriction on disclosure) through disclosure by sources other than BG RCI, having a right to disclose such information; or

3.3.4 was independently developed by COMPANY, any Affiliate and/or their employees, without access to BG RCI's Information, as evidenced by documentary records.

Specific items of information shall not fall within any exception merely because they are combined with more general information falling within any exception.

4 Exclusion of Liability

To the fullest extent permissible by law, BG RCI's liability shall be excluded.

In particular, but without limitation, BG RCI is neither liable for the accuracy and correctness of the study/studies listed in Annex 1, for the valuation (Klimisch code) of the studies if such valuation is given, nor for the acceptance of study/studies listed in Annex 1 by the ECHA during the dossier evaluation (according to Title VI REACH) nor for the transferability of any of the results to other substances.

5 Miscellaneous


- 5.1 Any modification or amendment of this Agreement requires a written instrument signed by all Parties hereto.
- 5.2 If any of the provisions of this Agreement shall be or become invalid in whole or in part, this shall not affect the validity of the remaining provisions. In such event, the parties shall endeavour, in trustful cooperation, to replace the invalid provision by a valid provision which most closely reflects the economic purpose of the invalid provision. The same shall apply mutatis mutandis to any gaps in this Agreement.
- 5.3 The validity, interpretation and performance of this Agreement and any dispute connected herewith shall be governed by and construed in accordance with the laws of Germany without regard to the conflict of laws principles thereof. Place of jurisdiction and performance shall be Heidelberg, Germany.

Heidelberg, *March 2, 2018*
(Date)


Dr. Maren Beth-Hübner

Berufsgenossenschaft Rohstoffe und chemische Industrie
Kurfürsten-Anlage 62
69115 Heidelberg
Germany

Bratislava, 12.2.2018
(Place/Date)


Ing. Martin Minárik

Company
Axxence Slovakia s.r.o.
Mickiewiczova 9, 811 070 Bratislava
Slovakia

Annex 1: List of Studies

Annex 2: Letter of Access for the registration under REACH

Annex 1: List of Studies

Substance: 3-methylbutan-1-ol		
CAS-No. 123-51-3		
or		
BG-No. 95		
	Letter of Access	
Study	with copy of the full study report	without copy of the full study report
(enter the abbreviation used in the table on our homepage)	(mandatory, give either one or the other)	
MNT	<input type="checkbox"/>	<input checked="" type="checkbox"/> 600 €
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
total	<input type="checkbox"/>	<input type="checkbox"/> 600 €

Legend			
Type of study		Species	
A	Ames test	cat	Cat
AP	Ames test with preincubation	dog	Dog
ALAR	Alarie test (sensory irritation)	gpig	Guinea pig
CBD	Covalent binding to DNA (adduct formation)	hams	Hamster
CLT	Combined long-term carcinogenicity study	mouse	Mouse
CTC	Cytogenetic test in vitro (cultures)	rat	Rat
CTV	Cytogenetic test in vivo	rbt	Rabbit
D01	Acute toxicity study (LD ₅₀ , LC ₅₀)	sgl	Syrian gold hamster
Dnn	Toxicity study with repeated administration (nn = 05 to 90 days)	Route of administration	
DnnCHE	Cholinesterase inhibition	caps	Gelatine capsules
DnnMHB	Methaemoglobin formation	der	Dermal
DnnNT	Neurotoxicity study (+ Irwin screen)	diet	Diet
DnnPP	Peroxisome proliferation	gav	Gavage
F	Follow-up study	ihl	Inhalation
FERT	Fertility study	ip	Intraperitoneal
HB	Haemoglobin adduct formation	orl	Oral
HPRT	Hypoxanthine phosphoribosyl transferase test	wat	Drinking water
		Status	
IRE	Eye irritation study	*	Sponsored by the chemical industry
IRS	Skin irritation study	* —	To get to know the Sponsor of the study please send an e-mail: toxikologische-bewertungen@bgrci.de
META	Metabolism/kinetic study	Examples	
MNT	Micronucleus test	D90NT-ori-rat	90-day neurotoxicity study, oral, rat
PROJ	Project	TERAF-ihl-rbt	Teratogenicity study (follow-up study), inhalation, rabbit
SENS	Sensitisation study	CTC*	Cytogenetic test in vitro (cultures): sponsored by the chemical industry
TERA	Embryotoxicity/teratogenicity study		
UDSC	Unscheduled DNA synthesis in vitro		
UDSV	Unscheduled DNA synthesis ex vivo in vitro		

**BG RCI**Berufsgenossenschaft
Rohstoffe und chemische IndustrieBG RCI - Prävention - KC Wissenschaftliche Fachreferate - Gefahrstoffe
und biologische Arbeitsstoffe - Postfach 10 14 80 - 69004 Heidelberg**Prävention**Kompetenz-Center
Wissenschaftliche Fachreferate
Gefahrstoffe und biologische ArbeitsstoffeEuropean Chemicals Agency
P.O. Box 400
00121 Helsinki
FINLANDIhr Zeichen:
Ihre Nachricht vom:
Unser Zeichen/ Dr.Bth/Hs
Mitgliedsnummer:
Ansprechperson: Dr. Maren Beth-Hübner
Telefon: 06221 5108-28451
Fax: 06221 5108-21199
E-Mail: maren.beth-huebner@bgrci.de
Dok-ID:

Datum:

*Chem 2, 2018***Letter of Access for the registration under REACH**

Dear Sirs,

BG RCI agrees that the study/studies listed in the Annex 1 to this Letter of Access may be used by the BG RCI Member Company

Name of company (hereinafter "COMPANY"):	Axxence Slovakia s.r.o.
BG RCI Member Company's registration number:	SK2020360034
Contact person:	Ing.Lubomira Raposova
Complete address:	Mickiewiczova 9, 811 07 Bratislava
E-mail address:	lubka.raposova@axxence.sk
Phone number:	+421903911941

in order to support its registration according to "Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)".

The right to use the study/studies is subject to the following restrictions:

1. The right of use is limited solely to fulfilling registration as well as other regulatory requirements under REACH.
2. The right of use is granted only to COMPANY and is not transferable to any other entity or person.
3. This Letter of Access shall under no circumstances be construed as granting COMPANY any property rights whatsoever in the studies.

Sincerely yours

Dr. Maren Beth-Hübner

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