BAUSCH Health

100 Life Sciences Parkway • Steinbach, MB R5G 1Z7
(204) 326-9000 / 4239
Fax: (204) 326-9800

March 28, 2019

Attention: Director of Environmental Approvals
Environmental Approvals Branch
Manitoba Sustainable Development
1007 Century Street
Winnipeg MB R2H 0W4
Phone: (204) 945-8321

Bausch Health Companies Inc., would like to have our Environmental Act License No.1364 R7 updated to reflect the change in our Solvent Drying process and to add Acetone to the list of chemicals used at the facility.

1. Description of Alterations.

1.1 Solvent Drying Process.

1.1.1 Overview of Bausch Health's Solvent Drying

The Dryers at the Facility are used to effectively dry the pre-mixed wet granulations (aqueous or solvent based) over a period. The drying process times vary from four (4) to twenty-four (24) hours and are done at temperatures ranging from twenty degrees celsius (20 ^{O}C) to sixty degrees celsius (60 ^{O}C), depending on the product. Because the wet granulation can be aqueous or solvent based, the Dryers are all equipped with a key switch on their exterior control panel which gives the user an option to send evaporated vapors to the Incinerator (solvent based product) or to the Atmosphere (aqueous based) for release **(Refer to Fig.1)**. Turning the switch to the Incinerator option opens the damper leading to the Incinerator, and closes the damper leading to the Atmosphere and vice versa. With the switch on the Incinerator, all evaporated solvent vapors travel through a ducting system and are directed to the Incinerator for ninety-nine point nine percent (99.9%) thermal destruction.

Fig.1: Dryer control panel

In addition, all Bausch Health employees assigned to the Drying Process are required to read *SOP PR-3201: O'Hara 400 Tray Dryer Oven & Tray Dryer Rack - Assembly, Operation, and Cleaning*. Section 7.4.1.3.1 of the SOP references the requirement to turn the key to Incinerator when handling solvent based product. Reading the SOP is mandatory, and upon completing the reading portion, operators complete test questions on Bausch's *SOP Student Online* to acknowledge that they have not only read the SOP but understand it. The operators, are also required to successfully complete training on the setup and operation of the Dryers and cannot operate them until they have been evaluated by their leader and can demonstrate their understanding of the Dryers' operation.

1.1.2 Requested Change

Based on the study conducted by our Tech Transfer Department on the Drying process for solvent based product, results from the study show that after 4 hours of drying, about 99.49% of the alcohol in the product would have evaporated. Bausch Health, as a result, would like to have the Drying process revised to allow, switching of the Dryer from incinerator to atmosphere, 4 hours into the drying process. By implementing this change, we anticipate an additional release of approximately 32kgs/yr. **(Refer to Attachment 01)**.

Note: During the drying process, not all alcohol is completely removed from the product. Drying is considered successful if residual alcohol left in product is Not More Than (NMT) 0.6%. As a result, the difference between the residual alcohol content at 4hrs (0.51%) and at 15 hrs (0.32%) was used to approximate the % alcohol released to the atmosphere at the end of drying.

1.2 Addition of Acetone.

1.2.1 Requested Change

Bausch Health would like to have Acetone added to the list of chemicals used at the development as it is now being used as a solvent in some of our Manufacturing Operations.

Alcohols currently listed in our Environmental Act Licence (Clause18):

- Methanol
- Isopropanol
- Ethyl alcohol
- Denatured ethanol

Acetone has been added to the same Preventative Maintenance schedules, SOP's and has the same environmental control measures as the other chemicals listed in Clause 18. These control measures prevent and treat emissions and also ensure the safe storage, handling and monitoring of Acetone.

2. **Requested Additional Information (Requested by Eshetu Bashada)**
   The total annual VOC emissions released to the atmosphere from the development as per clause 14 in the year 2015 was 2,967.50kgs **(Refer to Attachment 02)**. The year 2015 was used for this calculation, as this was one of our busiest years. The 2,967.50kg value is independent of the inadvertent releases from the Dryer incident that was reported to Manitoba Sustainable Development on December 27, 2018 and was addressed.

Regards,

Jordan Friesen, P.Eng. C.E.T.
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Steinbach MB R5G 1Z7
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Attachment 01: Bausch Health's Annual Dryer VOC Emission Estimation

Product	2015-Number of Lots produced	*Alcohol Dispensed (kgs)	Alcohol Type	**Alcohol Fugitive Emission Adjustment (kgs)	Process Airflow Rate at the Discharge Point (CFM)	Estimated VOC's Released to Atmosphere after 4hrs (kgs)
Carbidopa	0	11.00	Denatured Ethanol	9.90	3,000	0.00
Demser	0	11.06	Ethyl Alcohol 200	9.95	3,000	0.00
Diclofenac	12	83.07	IPA	74.76	3,000	1.70
Mephyton	2	15.70	Acetone	14.13	3,000	0.05
Nifedipine XL 30mg	42	81.60	IPA	73.44	3,000	5.86
Nifedipine XL 60mg	58	81.60	IPA	73.44	3,000	8.09
Nifedipine CC 30mg	33	81.60	IPA	73.44	3,000	4.60
Nifedipine CC 60mg	19	81.60	IPA	73.44	3,000	2.65
Nifedipine CC 90mg	12	86.40	IPA	77.76	3,000	1.77
Pentox	48	88.33	IPA	79.50	3,000	7.25
					Total VOCs released/yr after 4hrs of Drying	**31.99**

Note

1. As a worst-case scenario, Batch record data from 2015 was used for this calculation, as this was one of our busiest years.
2. 10% of the alcohol will be considered as Fugitive Emissions
3. Residual alcohol left in product as per Bausch Health should be NMT 0.6%
4. Residual alcohol values were obtained from the Study conducted by Tech Transfer REPORT #: RPV.B35.02 ADDENDUM 02

* Alcohol quantities were obtained from Bausch Health's Product Batch Records.

**This is the approximate amount of alcohol present in the product prior to Drying

Attachment 02: Total Annual VOC Emissions

Ethyl Alcohol 95% RS0006

	kg	kg	Type of air emission
Quantity Received in 2015	124060.00		
Alcohol used for MFG production	-105467.153	-105.467	TOX emissions
All other usage (cleaning, sampling)	-591.703	-59.1703	Fugitive emissions
End of Lot Adjustments	-262.708	-262.708	Storage emissions
SAP error corrections and status releases	0.000	0	
		-427.345	**TOTAL**

Methanol RS0002

	kg	kg	Type of air emission
Quantity Received in 2015	12940.00		
Alcohol used for MFG production	-8706.600	-8.71	TOX emissions
All other usage (cleaning, sampling)	-2901.780	-290.18	Fugitive emissions
End of Lot Adjustments	108.087	108.09	Storage emissions
SAP error corrections and status releases	0.000		
		-190.80	**TOTAL**

Denatured Ethyl Alcohol RS0018

	kg	kg	Type of air emission
Quantity Received in 2015	0.00		
Alcohol used for MFG production	-2078.19	-2.08	TOX emissions
All other usage (cleaning, sampling)	-64.86	-6.49	Fugitive emissions
End of Lot Adjustments	-52.60	-52.60	Storage emissions
SAP error corrections and status releases	0.00		
		-61.16	**TOTAL**

IPA RS0001

	kg	kg	Type of air emission
Quantity Received in 2015	40831		
Alcohol used for MFG production	-22954.640	-22.95	TOX emissions
All other usage (cleaning, sampling)	-18301.303	-1830.13	Fugitive emissions
End of Lot Adjustments	-338.31	-338.31	Storage emissions
SAP error corrections and status releases	0.000		
		-2191.39	**TOTAL**

Ethanol 200 Proof RS0010

	kg	kg	Type of air emission
Quantity Received in 2015	7282.00		
Alcohol used for MFG production	-6129.560	-6.13	TOX emissions
All other usage (cleaning, sampling)	-67.919	-6.79	Fugitive emissions
End of Lot Adjustments	-83.876	-83.88	Storage emissions
SAP error corrections and status releases	0.000		
		-96.80	**TOTAL**

Total VOC Emissions

	kg	kg	Type of air emission
Quantity Received in 2015	7282.00		
Alcohol used for MFG production	-6129.560	-145.34	TOX emissions
All other usage (cleaning, sampling)	-67.702	-2192.76	Fugitive emissions
End of Lot Adjustments	-41.267	-629.40	Storage emissions
SAP error corrections and status releases	0.000		
		-2967.50	**TOTAL**

Notice of Alteration Form

Manitoba
Sustainable Development

Client File No. : 3128.00	Environment Act Licence No. : 1364 R7

Legal name of the Licencee: Bausch Health Companies Inc.

Name of the development: Bausch Health Companies Inc.

Category and Type of development per Classes of Development Regulation:

Manufacturing — Manufacturing and industrial plants

Licencee Contact Person: Larry Thiessen
Mailing address of the Licencee: 100 Life Sciences Parkway
City: Steinbach Province: MB Postal Code: R5G 1Z7
Phone Number: (204) 326-9000 Fax: (204) 346-1596 Email: larry.thiessen@bauschhealth.com

Name of proponent contact person for purposes of the environmental assessment (e.g. consultant):
Thelma Mugova

Phone: (204) 326-9000 Fax:	Mailing address: 100 Life Sciences Parkway

Email address: Thelma.Mugova@bauschhealth.com

Short Description of Alteration *(max 90 characters)*:
Switch solvent drying to atmosphere after 4hrs. Add Acetone to clause 18

Alteration fee attached: Yes: ☑ No: ☐

If No, please explain:

Date: 2019-03-28	Signature:  Printed name: Thelma Mugova

A complete Notice of Alteration **(NoA)** consists of the following components:

- ☑ **Cover letter**
- ☑ **Notice of Alteration Form**
- ☑ **2 hard copies and 1 electronic copy of the NoA detailed report** (see "Information Bulletin - Alteration to Developments with Environment Act Licences")
- ☑ **$500 Application fee, if applicable** (Cheque, payable to the Minister of Finance)

Submit the complete NoA to:

Director
Environmental Approvals Branch
Manitoba Sustainable Development
1007 Century Street
Winnipeg, Manitoba R3H 0W4

For more information:

Phone: (204) 945-8321
Fax: (204) 945-5229
http://www.gov.mb.ca/sd/eal

Note: Per Section 14(3) of the Environment Act, Major Notices of Alteration must be filed through submission of an Environment Act Proposal Form (see "Information Bulletin – Environment Act Proposal Report Guidelines")

Bausch Health Companies Inc. 112914

SUPPLIER NO.	NAME			03/26/2019
10266200	MINISTER OF FINANCE			
INVOICE DATE	INVOICE NO.	OUR REFERENCE	REMARKS	NET AMOUNT
03/26/2019	ENVIRONMENTALLIC	1900714662		500.00
			TOTAL CAD	500.00

i-DNA™ REGISTERED SECURITY – SÉCURITÉ ENREGISTRÉE i-DNA™

BAUSCH Health

TD Canada Trust #0004-10202
55 King St. W.
Toronto, On M5K 1A2

CHEQUE NO. 112914

Bausch Health Companies Inc.
100 Life Sciences Parkway
Steinbach, MB CANADA, R5G 1Z7

DATE 03262019
MMDDYYYY

Pay *** FIVE HUNDRED CAD and ZERO Cents *** $ **********500.00*

TO THE ORDER OF
MINISTER OF FINANCE
ENVIRONMENTAL APPROVALS BRANCH
123 MAIN STREET, SUIT 160
WINNIPEG, MB CA R3C 1A5

BY

BY

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